Supreme Court, U. S.
FILED
JUN 18 1975
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

October Term, 1974

No. 74-1594

DIAPULSE CORPORATION OF AMERICA,
Petitioner,

—against—

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

COPAL MINTZ,
Counsel for Petitioner,
150 Broadway,
New York, N. Y. 10038.
(212) 227—7070

TABLE OF CONTENTS

PETITION

	Page
The Judgment Sought to be Reviewed	1
Opinions Below	2
Jurisdiction	3
Questions Presented	3
The Pertinent Statutes and Rules	4
The Case	8
Significant Differences Between the Two Judgments	9
The Grounds of this Application	15
Supporting Argument	21
I- The District Courts, After the Passing of the 10 Day or 30 Day Periods Provided in FRCP 50, 52 and 59, Are Without Power to Alter Final Judgments (Except To Correct Clerical Mistakes) Other Than to Vacate Them, in Whole or in Part	21
II- The Power Under FRCP 60(b)(5) and (6) is Exercisable Only Upon Evidence And Findings of Change of Circumstances Since The Date of the Judgment so Grave as to Justify Relief From the Operation of the Judgment; Here There are no Such Evidence or Findings.....	28

Page

III- The Reservation of Jurisdiction in the 1972 Judgment Does Not Dispense with the Requirement of Proof of Substantial Change. Indeed, Such a Reservation Does Not Vest Power Not Otherwise Possessed 31

IV- A Number of The Provisions in The 1974 Judgment Are Inconsistent With The Federal Food, Drug and Cosmetic Act and Are Contrary to Law 32

Conclusion 33

CITED CASES

Baum v. Baum, 40 A D 2d 1000 (2d Dept. 1972).. 25

Diapulse Corporation of America v. The Bircher Corp., 362 F 2d 736 (2d Circ. 1966) cert. denied 385 U.S. 801 2

Herpe v. Herpe, 225 N.Y. 323 (1919) 24

Humble Oil & Refining Co. v. American Oil Co., 405 Fed. 803 (8th Circ. 1968) 16

King-Seely Thermos Co. v. Aladdin Industries, Inc., 418 F. 2d 457 (2d Circ., 1969) 16

Klapprot v. United States, 335 U.S. 601(1949).. 23-4

Matter of City of New York, 39 A D 2d 669 (1st Dept., 1972) 25

Miltenberg & Samton, Inc. v. Falkingham, 273 App. Div. 631 (1st Dept. 1948) 25

People v. Jackson, 307 N.Y. 271 (1954) 25

	Page
Ridley v. Phillips Petroleum Co., 427 F 2d 19 (10th Cir., 1970)	16
Schildhaus v. Moe, 335 F 2d 529 (2d Circ. 1964)	16,29
Securities & Exchange Commission v. Thermo-dynamics, Inc., 464 F 2d 457 (10th Circ., 1972)	16
System Federation v. Wright, 364 U.S. 642 (1961)	16,28-9
United States v. "Cameron Spitler"...261 F. Supp. 243 (D.Neb., 1966)	19
United States v. Diapulse Corporation of America, 269 F. Supp. 162 (D.Conn. 1967) aff'd. 389 F 2d 612 (2d Circ. 1968)cert. denied 392 U.S. 907	2
United States v. Diapulse Corporation of America, 457 F 2d 677 (2d Circ. 1972)	2
United States v. Diapulse Corporation of America, 485 F 2d 677 (2d Circ. 1973) cert. denied, 94 S.C. 938 (4/15/74	1,2
United States v. United Shoe Manufacturing Corp., 391 U.S. 244 (1968)	17,25-7
United States v. Sullivan, 332 U.S. 689 (1947)	19
United States v. Swift & Co., 286 U.S. 106 (1932)	16,28
United States v. Ten Cartons... Hoxey Tablets, 152 F. Supp. 360 (W.D.Pa. 1957)	19

STATUTES AND RULES

		Page
CFR: 21 CFR 1.106	Appendix	39
Federal Food, Drug and Cosmetic Act, 21 U.S.C. Chapter 9, Sections 321, 331, 332, 334, 352, 374	Appendix	35-39
Federal Rules of Civil Procedure		
Rule 50		21
50(b)		4, 15
52		21
52(b)		4-5, 15
59		5, 15
59(a)		5
59(d)		5
59(e)		6
60		6, 15, 21
60(a)		6, 21
60(b)		6-7, 15, 21, 22,23
New York Civil Practice Law and Rules Sections 4404, 4405, 5015		25

TEXTS

7 Moore's Federal Practice, 2d Ed...	22

	Page
Webster's New World Dictionary	22
Webster's Third New International Dictionary - Unabridged	22-23

APPENDIX

Related Provisions of the Federal Food, Drug and Cosmetic Act	35
Sec. 321 Definitions	35
" 331 Prohibited Acts	35
" 332 Injunction Proceedings - Jurisdiction	36
" 334 Seizure - Grounds and Jurisdiction	36
" 352 Misbranded drugs and devices	36
" 374 Inspection - Right of agents to enter; scope of inspection; notice; promptness; exclusions	37
Pertinent provisions of 21 CFR	39
Opinion (2d. Circ., 1975)affirming Judgment of 7/18/74	40
Order, 2d Circ. affirming Judgment of 7/18/74	43
Permanent Injunction 7/18/74 (Dooling,J.)	44
Permanent Injunction 7/18/72 (Rosling,J.,)	58

Page

Memorandum (Dooling, J., 5/7/74) incorporating findings of fact and Order 63

Decision (Rosling, J., 6/9/72) after Trial 101

Decision (Rosling, J., 11/11/71) granting motion for preliminary injunction 143

Findings and order (Rosling, J., 12/8/71) of preliminary injunction 170

Opinion, 457 F 2d 25 (Circ. 2d, 3/20/72) affirming preliminary injunction 186

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1974

No.

DIAPULSE CORPORATION OF AMERICA, Petitioner

v.

UNITED STATES OF AMERICA

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioner, Diapulse Corporation of America, respectfully prays that a writ of certiorari issue to review the affirmance by the United States Court of Appeals for the Second Circuit, on March 21, 1975, of a judgment of "Permanent Injunction" of the United States District Court for the Eastern District of New York (John F. Dooling, Jr., J.), entered July 18, 1974, which superseded a final judgment of "Permanent Injunction" of the same Court (by the late Rosling, J.) entered two years previously in the same action, on July 18, 1972. The latter judgment had been affirmed by the United States Court of Appeals (485 F 2d 677) and certiorari thereof had been denied by this Court (94 S. Ct. 1938).

The July 18, 1974, judgment of Permanent Injunction (which is the subject of this petition) is far more

drastic and extensive than the preceding judgment of "Permanent Injunction" of July 18, 1972.

OPINIONS BELOW

The opinion of the Court of Appeals is reproduced at pages 40-2 infra. It has not as yet been reported. The decision of the District Court entitled, "Memorandum Incorporating Findings of Fact and Order", dated and filed May 7, 1974, is not reported; it is reproduced at pages 63-100 infra.

The superseded judgment of July 18, 1972, and The District Court's opinions which preceded it, are not reported; they are reproduced at pages 58-185 infra. The affirmance of that judgment, as already noted, is reported in 485 F 2d 677. There was no opinion.

Before the rendition of the July 18, 1972 judgment, there were two pendente lite injunctions, the second of which was affirmed with an opinion reported in 457 F 2d 25 (2d Circ. 1972*). It is reproduced at pages 186-192.

* Other reported decisions involving petitioner's device Dipaulse are: Diapulse Corporation of America v. Bircher Corp., 362 F. 2d 736 (1966), cert. denied, 385 U.S. 801, a libel action determined in favor of Diapulse; U.S. v. Diapulse Manufacturing Corp., 269 F. Supp. 162 (D. Conn., 1967), aff'd 389 F. 2d 612 (2d Cir.), cert. denied 392 U.S. 907 (1968), an FDA seizure action.

JURISDICTION

The judgment of the Court of Appeals was entered on March 21, 1975. This petition is being filed within the ninety days thereafter. The jurisdiction of this Court is invoked under U.S.C. 1254 (1).

The appeal to the U.S. Court of Appeals was taken under 28 U.S.C. 1291, as an appeal from a final judgment of a U.S. District Court. That appeal was taken in due time. The resultant jurisdiction of the Court of Appeals was not questioned. The action in the U.S. District Court for the Eastern District of New York was brought by the United States of America, the complaint alleged, under Section 302(a) of the Federal Food, Drug and Cosmetics Act (21 U.S.C. 332(a)), to restrain violations of Sections 301(a) and (k) of the Act, 21 U.S.C. 331(a) and (k).

QUESTIONS PRESENTED

1. Did the District Court have power, in 1974, to enter a new judgment superseding the final judgment of "Permanent Injunction" entered two years previously and affirmed by the Court of Appeals, containing additional and different restraints, impositions and requirements?

2. Did the District Court have power to include provisions beyond the purview of the complaint, both in its allegations and prayer for relief?

3. Did the District Court have power to do so in the absence of findings of vital changes in circumstances?

BLEED THROUGH

POOR COPY

4. Did the District Court vest itself with power not provided by the Rules by inserting in the 1972 judgment a provision retaining jurisdiction

> "for the purpose of enforcing or modifying this Permanent Injunction, and ... of granting such additional relief ... as may hereafter appear necessary or appropriate" ?

THE PERTINENT STATUTES AND RULES

Amendment of, and relief from, judgments or orders are provided for in FRCP 50(b), 52(b), 59 and 60.

Rule 50(b) entitled "Motion for Judgment Notwithstanding the Verdict" has no relevance to this appeal other than furnishing a contrast to Rule 60(b). A motion thereunder must be made "Not later than 10 days after entry of judgment". The moving party

> "may move to have the verdict and judgment entered thereon set aside and to have judgment entered in accordance with his motion for a directed verdict. ... the court may allow the judgment to stand or may reopen the judgment and either order a new trial or direct the entry of judgment as if the requested verdict had been directed."

Additional ancillary powers are set forth in section (c).

Rule 52(b) provides, so far as relevant to the consideration of this case:

"(b) Amendment. Upon motion of a party made not later than 10 days after entry of judgment the court may amend its findings or make additional findings and may amend the judgment accordingly. ..."

Rule 59, entitled "New Trials; Amendment of Judgments" provides, in part, as follows:

"(a) Grounds. A new trial may be granted to all or any of the parties and on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States; and (2) in an action tried without a jury, for any of the reasons for which rehearings have heretofore been granted in suits in equity in the courts of the United States. On a motion for a new trial in an action tried without a jury, the court may open the judgment if one has been entered, take additional testimony, amend findings of fact and conclusions of law or make new findings and conclusions, and direct the entry of a new judgment. [Emphasis added] *

* * * * *

(d) On initiative of Court. Not later than 10 days after entry of judgment the court of its own initiative may order a new trial for any reason for which it might have granted a new trial on motion of a party. After giving the parties notice and an opportunity to be heard on the matter, the court may grant a motion for a new trial, timely served, for a reason not stated in the motion. In either case, the court shall specifyin the order the grounds therefor. [Emphasis added]

---

* Subdivision (b) requires service within ten days and (c) for an extension of "not exceeding 20 days".

(e) Motion to Alter or Amend a Judgment. A motion to alter or amend the judgment shall be served not later than 10 days after entry of the judgment." [Emphasis added]

Rule 60, in its entirety, provides as follows:

"Relief from Judgment or Order

(a) Clerical Mistakes. Clerical mistakes in judgments, orders or other parts of the record and errors therein arising from oversight or omission may be corrected by the court at any time of its own initiative or on the motion of any party and after such notice, if any, as the court orders. During the pendency of an appeal, such mistakes may be so corrected before the appeal is docketed in the appellate court, and thereafter while the appeal is pending may be so corrected with leave of the appellate court.

(b) Mistakes, Inadvertence; Excusable Neglect; Newly Discovered Evidence; Fraud, etc. On motion and upon such terms as are just, the court may relieve a party or his legal representative from a final judgment, order, or proceeding for the following reasons: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b); (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct of an adverse party; (4) the judgment is void; (5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application;

> or (6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken. A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court to entertain an independent action to relieve a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C. § 1655, or to set aside a judgment for fraud upon the court. Writs of coram nobis, coram vobis, audita querela, and bills of review and bills in the nature of a bill of review, are abolished, and the procedure for obtaining any relief from a judgment shall be by motion as prescribed in these rules or by an independent action." [Emphasis added]

Also pertinent are various provisions of the Food, Drug & Cosmetics Act (Title 21 of the U. S. Code). Since those are of secondary importance, they are reproduced in the appendix of this brief at pages 35-9 infra.

THE CASE

This action was commenced in 1968. It was tried between June 7, 1971 and February 10, 1972. A decision of 41 pages followed on June 9, 1972, which incorporated by reference earlier interlocutory findings and conclusions set forth in writings aggregating over 80 pages (see pages 101-185 infra).* A final judgment of "Permanent Injunction", dated July 15, 1972 was filed July 18, 1972 (58-62). That judgment was affirmed by the Court of Appeals, Second Circuit on October 24, 1973, without opinion (485 F. 2d 677). On April 15, 1974, this Court denied a petition for certiorari (94 S. Ct. 1938).

On August 1, 1973 the plaintiff instituted a criminal contempt proceeding against the defendant and two of its officers, charging that they violated the injunction of July 18, 1972 in a number of respects and the preliminary injunction in one respect - all between July 19, 1972 and September 25, 1972. That contempt proceeding was tried before District Judge John

---

* Except when otherwise indicated, numerals up to 34 refer to pages of this brief and/or after 34 to pages of the Appendix which follows.

F. Dooling, Jr., and a jury. After five days of trial the proceeding was dismissed at the end of the Government's case (63, 91-2).

Nowhere is there a claim or suggestion of any conduct after September, 1972, on the part of the defendant or its personnel inconsistent with scrupulous observance of the injunction.

Judge Dooling, however, expressed the view that the terms of the judgment should be clarified to make its terms more definite and certain so as to eliminate a repetition of controversy as to the meaning of the injunctive provisions. Upon consent of the parties, further hearings were held. On May 7, 1974, Judge Dooling filed a 39-page "Memorandum Incorporating Findings of Fact and Order" (63-100).

That order directed that "proposed modifying paragraphs [modifying the July, 1972 judgment] within limits indicated by the sense" of his decision, "be settled on notice".

There eventuated the 13 page "Permanent Injunction" (44-57) which is the subject of this appeal, in replacement of the five page 1972 judgment (58-62).

Significant Differences between the Two Judgments

1. The 1972 five page judgment related exclusively

BLEED THROUGH

to the labeling or branding of a device described as "an electromagnetic generator similar to conventional medical diathermy but differing from it in that its output is pulsed and in that it lacks the energy output of conventional medical diathermy" (58) and "permanently enjoined" the defendant and its officers, etc. "from violating 21 U.S.C. 331(a) and (k) by directly or indirectly" causing "to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce, or otherwise disposed of," any such device, "in whole or in part, assembled or unassembled, unless and until the said defendant assembles the scientific evidence on which labeling of the device is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106, and the defendant submits such evidence and labeling to the Food and Drug Administration and obtains approval thereof in writing" (59-61).

The 1974 judgment (44-57) extends the prohibitions to, and includes therein, devices with all the energy output of conventional medical diathermy (see sections II(E)(3) at p. 46 infra, and III at pp. 46-8 infra) and prohibits the defendant from interstate shipping of such devices "both in whole or in part, whether assembled or unassembled and components, parts, accessories, assemblies

and subassmblies, usable or adaptable to create defined devices or to convert other devices into defined devices" "unless and until the said defendant assembles adequate scientific evidence on which labeling of said prohibited devices is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106(d), and the defendant submits such evidence and such proposed labeling to the Food and Drug Administration, Rockville, Maryland, and obtains approval thereof in writing: . ." (at 48-9; emphasis added).

In contrast, all other manufacturers and distributors freely market interstate conventional diathermy devices whether or not and regardless of how pulsed with standard extensive therapeutic claims. Thus, by the 1974 judgment, unlike the 1972 judgment, petitioner is prohibited from marketing devices which were not the subject of his complaint and which were not included in the 1972 judgment and all others may freely market without FDA clearance or approval. (See 85, 88-92)

2. The 1974 judgment, as hereinabove noted, incorporates a provision not contained in the 1972 judgment, reading: "any of such prohibited devices in the possession

of any practitioner licensed by law to use or order the use of any of said prohibited devices shall be deemed to be held for sale". (48)

3. The 1974 judgment, unlike the 1972 judgment, mandated that the defendant to "cause" previously shipped Diapulses "to be returned to the possession of the defendant ... at defendant's expense" (52) and either elect "whether to attempt to bring the said returned devices into compliance with the law by relabeling or modification" if and as approved by the FDA, or "whether to destroy or salvage (for other than device purposes) the said returned devices;" but "not commence such destruction or salvaging operations until it [defendant] has received authorization in writing" from the FDA (53) and "until duly authorized representatives of the Food and Drug Administration shall have had free access thereto" to examine or inspect, and FDA "in writing" releases "said devices for shipment, sale or other disposition" (53-4).

Those provisions probably have lapsed by reason of the time specifications in respect thereto.

4. The 1974 judgment, unlike the 1972 judgment, requires the defendant to inform FDA of the location of each of the offices, plants, factories, warehouses, storage

facilities, or other establishments used by the said defendant for the manufacturing, assembling, processing, packing, transporting, or holding of any device or which is used by the said defendant to hold any equipment, finished and unfinished materials, containers, labeling, records, files or other papers bearing on the manufacturing, assembling, processing, packing, transporting, or holding of any devices; and shall thereafter submit notice in writing to the Food and Drug Administration, Rockville, Maryland, as to each disposition or acquisition of such establishments within ten days of each such occurrence." (Section V(A) at 54)

5. The 1974 judgment, unlike the 1972 judgment, mandates the defendant also to grant FDA "free access" to any of its establishments "at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in place." (Section V(B) at 54-5;emphasis added)

6. In addition, the 1974 judgment contained directions for mailing of copies thereof and notices "to each and every person known to the defendant to have purchased, leased or have in his possession a Diapulse device" and also to other specified categories of persons. However, since those provisions have been complied with, they are pertinent only as additional indices of the nature and scope of the rewriting of the 1972 judgment.

7. Even in impliedly recognizing that "shipment or other delivery [solely] for investigational or research purposes" is not introduction "in commerce," Judge Dooling circumscribed the exclusion thereof from the injunction by requiring advance submissions to the FDA of minutely detailed information of the proposed investigation or research project, by whom (with all their professional qualifications), where, when, how and how long and by requiring periodic and final reports to FDA. (50-51)

The Common Provision in Both Judgments

The 1974 judgment, like the 1972 judgment, retains jurisdiction in the court "for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate." (56, 62)

THE GROUNDS OF THIS APPLICATION

(1). As appears from the Rules reproduced at pages 4 - 7 supra, post-verdict and post-judgment relief is provided for in Rules 50(b), 52(b), 59 and 60 of the Federal Rules of Civil Procedure (hereinafter referred to as FRCP).

Rules 50(b), 52(b) and 59 give district courts wide power over verdicts and judgments on motions made within ten days after entry of judgment or on the court's own initiative within ten days after entry of judgment.

Rule 60(a) provides for correction of "clerical mistakes".

The only authority beyond the foregoing is set forth in Rule 60(b). That subsection provides that "the Court may relieve a party, ... from a final judgment" on various specified grounds including that "it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment." (Emphasis added)

In this case, the court did not relieve the defendant from the prior final judgment or any part thereof; it did the converse, it expanded and made more drastic the 1972 restraints and it added restraints. (See pp.9-14 supra)

Thus, there are here presented the questions of (i) whether, "may relieve", means also may add and may impose; (ii) if not, whether, in the face of the comprehensive provisions embodied in the above mentioned four Rules comprised of eleven sections, the district courts have also inherent power to supersede an affirmed final judgment with a more drastic one; and (iii) if there is such a power what are its qualifications (if any) and limitations (if any).

United States v. Swift & Co., 286 U.S. 106 (1932), System Federation v. Wright, 364 U.S. 642 (1961), Schildhaus v. Moe, 335 F. 2d 529 (2d Cir. 1964), Humble Oil & Refining Co. v. American Oil Co., 405 F. 2d 803 (8th Cir., 1969), Ridley v. Phillips Petroleum Co., 427 F. 2d 19 (10th Cir., 1970), King-Seely Thermos Co. v. Aladdin Industries, Inc., 418 F. 2d 31 (2d Cir., 1969), and Securities and Exchange Commission v. Thermodynamics, Inc., 464 F. 2d 457 (10th Cir., 1972), were all applications for relief from injunctions. In two of them, the applications were denied and the denials were affirmed; in System Federation, the denial was reversed by this Court; in Humble Oil the denial of the application was affirmed; in Schildhaus the vacatur was reversed; in King-Seely the denial was remanded for further consideration. In none of those cases was a

final injunction made more stringent.

United States v. United Shoe Machinery Corp., 36 U.S. 244 (1968), cited and relied on by the Court of Appeals (and discussed fully at pages 25-27 infra) was a complex anti-trust case where the provisions of the judgment failed to achieve the decreed elimination of the complained of monopoly. This Court held that the District Court "should proceed to determine whether the relief [in the original judgment] has met the standards which this Court has prescribed. If it has not, the District Court should modify the decree so as to achieve the required result."

If, as this counsel believes, reliance on United Shoe Machinery is misplaced, the decision of the Court of Appeals in this case, if left standing may lead to the unsettling of judgments and a practice by agencies of the Government, instead of bringing new actions for alleged new wrongs, to move for additional restraints way beyond those sought in the tried complaint, without new pleadings and without new evidence.

It is submitted that there is thus here presented an important question of orderly procedure, due process and reasonable construction of statutory provisions, which call for this Court's consideration.

(2). The disregard, as petitioner sees it, of the perimeters of Rule 60(b) has led the District Court to include, and the Court of Appeals to affirm, a provision not contained in the preceding judgment, reading (see page 48 infra):

> "any of such prohibited devices in the possession of any practitioner licensed by law to use or order the use of any of said prohibited devices shall be deemed to be held for sale."

That has no application to the defendant. Since the defendant is a manufacturer and not a practitioner, that provision has no application to the defendant nor does it relate to any issue in the case. It was not the subject of a hearing; it is sheer obiter dictum. Its effect, if not purpose, can be only to prejudice the rights of persons who are not before the court - practitioners who may resist or desire to resist seizure on the ground that instruments that they use in the course of their practice -- e.g. their stethoscopes and surgical instruments which they use but do not part with -- are not "held for sale" and thus the Diapulse device which they own and use on patients, but do not part with, are not "held for sale" so long as they are held for the purpose of treating patients, and thus are not within the "seizure" jurisdiction of the district courts.

The Court of Appeals, by approvingly saying (41-2),

> "... such devices used in the treatment of patients may properly be considered 'held for sale' within the meaning of the Food, Drug and Cosmetics Act, 21 U.S.C... §331(k)"

very seriously compounds that deviation from the issues of the action, that aside, so to speak.

In regard to whether that pronouncement is legally correct, the two district court cases cited by the Court of Appeals afford scant support. In one of them, U. S. v. Ten Cartons ... Hoxey Tablets, 152 F. Supp. 360 (W.D. Pa., 1957), the tablets when seized were in the possession of a clinic for delivery to patients, on doctor's prescriptions, according to be taken home for consumption/to specified directions. That clearly has no application to a device which does not ever leave a practitioner's office or his possession. Only U. S. v. "Cameron Spitler", 261 F. Supp. 243 (D. Neb., 1966) and only that case supports the Government's position. Such a single district court decision, distorting "sale" to comprehend an owner's use without (even momentary) transfer of title or possession is hardly persuasive authority. (Cf. U. S. v. Sullivan, 332 U. S. 689 (1947).

The gratuitous inclusion of that obiter dictum for no apparent reason other than to affect parties

who are not before the court, petitioner respectfully urges, is a departure from the accepted and usual course of judicial proceeding, which the Court of Appeals has sanctioned, which calls for the exercise of this Court's power of supervision.

(3). Even if a district court has the power to modify, as distinguished from relieving from a judgment, by making it more drastic and by including additional restraints, there is still a question of how far can a court go in doing that without offending due process. In this case, a hearing was held for the purpose, as petitioner understood it, of arriving at clarifications and possible alleviations -- not extensions and more restraints. There was no new pleading, no expansion of the prayers of the complaint. Nor is the new judgment predicated upon adequate new findings, as is pointed out infra at 29-31.

(4). The foregoing, it is respectfully urged, presents questions which are vital to the administration of justice in accordance and in conformity with duly ordained Rules of Procedure and applicable statutes.

SUPPORTING ARGUMENT

I

THE DISTRICT COURTS, AFTER THE PASSING OF THE 10 DAY OR 30 DAY PERIODS PROVIDED IN FRCP 50, 52 and 59, ARE WITHOUT POWER TO ALTER FINAL JUDGMENTS (EXCEPT TO CORRECT CLERICAL MISTAKES) OTHER THAN TO VACATE THEM, IN WHOLE OR IN PART.

(1). As appears at pages 4-7, 14 supra, Rule 60, as amended in 1948, is the only rule which deals with amendment of final judgments after the expiration of the ten and thirty day periods provided for in Rules 50, 52 and 59.

It is noteworthy that Rules 50, 52 and 59, notably the latter, say that the court may "open the judgment ... take additional testimony, amend findings of fact and conclusions of law or make new findings and conclusions, and direct the entry of a new judgment", and Rule 60(a), in referring to "clerical errors", uses the words, "may be corrected" (emphasis added). In marked contrast, Rule 60(b) does not contain, in any form, the verbs, "amend", "alter", "make new findings and conclusions", "direct the entry of a new judgment".

Rule 60 is captioned "Relief from judgment or order" (emphasis added). Subdivision (a) thereof relates only to "clerical errors"; it provides that they "may be corrected" and stipulates no time limitations.

Subdivision (b), however, concerned with substantive changes, very restrictively provides:

> "on motion and upon such terms as are just, the Court may relieve a party or his legal representative from a final judgment, order or proceeding for the following reasons: ..."

We all know that "relieve from" does not also mean "add to", just as we know that "subtract" does not mean also "add". There is no ambiguity in the meaning of the phrase "relieve from". The dictionaries define "relieve" to mean, "to free from a burden ...to bring about ... removal or alleviation ... make less burdensome or afflicting, mitigate, lessen, alleviate ... to set free from an obligation, condition or restriction ... to ease of an imposition, burden, wrong, or oppression by judicial or legislative interposition ..." (Webster's Third New International Dictionary - Unabridged); "to ease, lighten, reduce ... to free ... to set free from a burden, obligation" (Webster's New World Dictionary).

As synonyms, Webster's New International lists "alleviate, lighten, assuage, mitigate, allay".

(2). Is there inherent power beyond and different from those provided in the Rules?

Moore's Federal Practice points out that original

Rule 60(b) was amended because it lacked exclusivity (Vol. 7, 2d Ed., p. 91).

The Advisory Committee is quoted to have reported that the committee deemed it "obvious that the rules should be complete and define the practice with respect to any existing rights or remedies to obtain relief from final judgments" (at 207; emphasis added) and thus should be amended to "permit, either by motion or by independent action, the granting of various kinds of relief from judgments which were permitted in the Federal Courts prior to the adoption of these rules." (At p. 201; emphasis added). Moore's adds that amended Rule 60(b) "is a deliberate balancing of the competing principles of finality and relief from unjust judgments" (at p. 203; emphasis added), and "operates both as a grant and limitation upon power of the District Court to give relief from a final judgment." (At p. 340; emphasis added)

This Court, in Klapprott v. U.S., 335 U.S. 601 (1949), in setting aside a judgment entered several years before the amendment of Rule 60(b), relied on Clause 6 of that Rule as amended as the district court's source of power, saying, at pages 614-615:

> "In simple English - - [it]vests power in courts adequate to enable them to vacate judgments

> whenever such action is appropriate to accomplish justice." (Emphasis added.)

The tenor of Justice Black's opinion ruled out inherent power and directed that the judgment be set aside under Rule 60(b).

It is fair to infer that the prolonged and intense study by the Advisory Committee led it to conclude that there never was an inherent power to make a final judgment more stringent or more onerous, and since it was concerned with procedure and not substantive law, deliberately limited 60(b) to "relief from."

It may not be amiss to note that the New York courts consistently held that they lacked inherent power to change final judgments as distinguished from setting them aside. Thus, the New York Court of Appeals wrote in 1919, in Herpe v. Herpe, 225 N.Y. 323, at 327-8:

> "The rule has long been settled and inflexibly applied that the trial court has no revisory or appellate jurisdiction to correct by amendment error in substance affecting the judgment. It cannot, by amendment, change the judgment in matter of substance for error committed on the trial or in the decision, or limit the legal effect of it to meet some supposed equity subsequently called to its attention or subsequently arising. It cannot correct judicial errors either of commission or omission. Those errors are, under our system of procedure, to be corrected either by the vacating of the judgment or by an appeal [citing cases]. ."(emphasis added)

See also People v. Jackson, 307 N.Y. 271, 275 (1954); Miltonberg & Samton, Inc. v. Falkingham, 273 App. Div. 631 (1948); Matter of City of New York, 39 A.D. 2d 669 (1st Dept., 1972); Baum v. Baum, 40 A.D. 2d 1,000, 1,001 (2nd Dept., 1972).

In 1955, by amendment of the then New York Civil Practice Act and Rules of Civil Procedure, the power of the courts was broadened to approximate the provisions of the FRCP as amended in 1948. Those provisions are presently contained in the New York Civil Practice Law and Rules, §§4404, 4405 and 5015. The last mentioned section, entitled, "Relief from judgment or order" provides: "The court which rendered a judgment or order may relieve a party from it," on five specified rather narrow grounds. The New York courts do not assert a power to substantively alter final judgments, after the lapse of the short periods of time specified in the statutes, other than to vacate them.

(3). Precedents

The pertinent cases are referred to at pages 16-17 supra. Since the Court of Appeals relied exclusively on U.S. v. United Shoe Machinery Corp., 391 U.S. 244 (1968), it is important to note that the phrase "inherent power", does not appear in this Court's opinion. That was a complex

antitrust case where the complaint sought the effective breaking-up of a charged pervasive monopoly. Upon finding that the charged monopoly existed, the district court, in an endeavor to reestablish a competitive market, fashioned a complex decree (other than that proposed by the Government) with a provision calling for reports and a judicial review ten years later on whether and to what extent the directed measures achieved the decreed result.

This Court was informed that in fashioning the decree the district court had "proceeded on the premise that relatively mild remedies should be tried as a first resolution and that the possibility of more drastic measures should be held in abeyance." This Court found confirmation of that statement in the express requirement for a "report after ten years of experience under the decree, and contemplated that petitions for modifications might be filed 'in [view of the decree's] effect in establishing workable competition.'"

Consequently, when the Government asserted that the decree had failed "to recreate a competitive market," and petitioned for relief to effect that purpose, this Court held that the district court "should proceed to determine whether the relief in this case has met the standards which this Court has prescribed".

Manifestly, there is no parity between that case and this case. The injunctive provisions of the Food and Drug Act are very limited (see 35-6). The complaint in this case (see 100-1, also 68-70, 84-9) was limited to allegations concerning the athermal "Diapulse" and therapeutic claims for it. In the affirmance of Judge Rosling's temporary injunction (457 F 2d 25 , 26; infra 187) "Diapulse" is described as "a pulsed high frequency generator similar to a conventional diathermy unit but with a lower output*, intended to create a unique athermal effect" (see also, 69, 85-90). The prayer for relief was for an injunction under section 332(a) not to violate the misbranding prohibitions of section 331(a) and (k) and also enjoining interstate shipment of the "said Diapulse device or any similar device" unless and until FDA approves its labelling (105-6). All of that was granted by the 1972 judgment of "Permanent Injunction". The district court could have gone no further.

It is clear beyond argument that the express and sole objective of the complaint was to restrain petitioner's marketing of its athermal deviates from conventional diathermy. Therefore, the 1974 extension of the injunction to conventional diathermy units with conventional labelling, went and goes way beyond the basis and purview of the action.

* The language in the complaint was "but it lacks the energy output of a conventional medical diathermy unit. It purports to achieve therapeutic results without generating heat".

BLEED THROUGH

POOR COPY

II

THE POWER UNDER FRCP 60(b)(5) and (6) IS EXERCISABLE ONLY UPON EVIDENCE AND FINDINGS OF CHANGE OF CIRCUMSTANCES SINCE THE DATE OF THE JUDGMENT SO GRAVE AS TO JUSTIFY RELIEF FROM THE OPERATION OF THE JUDGMENT; HERE THERE ARE NO SUCH EVIDENCE OR FINDINGS.

(1). In United States v. Swift & Co., supra, 286 U.S. 106 (1932), this Court reversed the District Court's partial relaxation of the continuing injunction precisely because it had not been established that the injunction had "turned through changing circumstances into an instrument of wrong." (See pp. 114-115) At page 119, this Court said:

> "There is need to keep in mind steadily the limits of inquiry proper to the case before us. We are not framing a decree. We are asking ourselves whether anything has happened that will justify us now in changing a decree. The injunction, whether right or wrong, is not subject to impeachment in its application to the conditions that existed at its making. We are not at liberty to reverse under the guise of readjusting. Nothing less than a clear showing of grievous wrong evoked by new and unforeseen conditions should lead us to change what was decreed after years of litigation with the consent of all concerned."

Those criteria were repeated in System Federation v. Wright, 364 U.S. 642, 647-8 (1961), namely, there must appear such "significant changes in law or facts" which demonstrate the need for change.

> "A balance must thus be struck between the policies of res judicata and the right of the court to apply modified measures to changed circumstances."

In Schildhaus v. Moe, 335 F. 2d 529 (2d. Cir., 1964), the Court of Appeals for the Second Circuit, through Friendly, C.J., said (at p. 530):

> "... Rule 60(b) is 'no invitation to relitigation of matter adjudged by the original judgment.' 7 Moore, Federal Practice ¶60.26 [4], p. 288 (1955)."

(2). The 1972 judgment in this case was rendered after a very lengthy trial and several lengthy and detailed decisions. The present judgment purports to be "in accordance with the Findings of Fact and Conclusions of Law" in those prior decisions of December 8, 1971, and June 9, 1972, and the findings and conclusions, dated May 7, 1974 (44). The latter comprises over 38 pages of legal cap (63 - 99). For the most part it is a recital of pre-judgment events and determinations including extensive quotations from Judge Rosling's previous adjudications.

Of post-judgment occurrences, only the following appear: Defendant had evolved a "P/EmF" (intended to have all of the thermal capabilities of conventional diathermy) which it never marketed or tried to market. In the belief that the device would have those capabilities, defendant

prepared small kits of wires and small parts to enable possessors of Diapulses to convert their devices, if they so desired, to P/EmF's, and in July-August, 1972, shipped several hundred of those kits to such possessors. (63-5, 74-83).). There is no claim and no finding that there were any shipments beyond those. Claiming that those shipments violated the judgment of July 18, 1972, the plaintiff, one year later, on August 1, 1973, instituted a criminal contempt proceeding (63-4). After four or five days of trial before Judge Dooling and a jury, the Judge dismissed the petition because "it would be legal error to submit the case to the jury since the jury could not, on the evidence, find beyond a reasonable doubt" that the complained of shipments were 'articles of device known as DIAPULSE, or any similar articles of device. . .in whole or in part, assembled or unassembled' within the required plain meaning of the permanent injunction" (91-2).

Judge Dooling, however, found dissatisfaction with the P/EmF and associated literature (74-90) . He arrived at a similar conclusion in respect to another modality which defendant submitted to FDA for approval (90-91). There was no claim and there is no assertion or finding in the May 7, 1974, memorandum of any attempt whatsoever or any

intention, after early August, 1972, to make, without FDA approval, any interstate shipment of anything whatsoever, either devices, parts, equipment or literature. None was made other than a number of submissions to the FDA in compliance with the 1972 injunction.

III

THE RESERVATION OF JURISDICTION IN THE 1972 JUDGMENT DOES NOT DISPENSE WITH THE REQUIREMENT OF PROOF OF SUBSTANTIAL CHANGE. INDEED, SUCH A RESERVATION DOES NOT VEST POWER NOT OTHERWISE POSSESSED.

(1). In United States v. Swift & Co., supra, 286 U.S. 106, the following appears at pages 111-112:

> "The [original] decree closed with a provision whereby jurisdiction of the cause was retained for the purpose of taking such other action or adding at the foot such other relief 'as may become necessary or appropriate for the carrying out and enforcement' thereof, 'and for the purpose of entertaining at any time hereafter any application which the parties may make' with reference thereto."

Nevertheless, this Court held that no change lawfully could be made in the absence of "change in circumstances" sufficient "to justify" the changes which the district court had made.

It follows that reservation of jurisdiction, per se, does not vest power not otherwise possessed.

It is submitted that a court cannot by its own edict give itself or extend a jurisdiction or a power it would not otherwise possess. It is firmly established, of course, that except (in some instances) as to jurisdiction over a person, consent cannot vest in a court a jurisdiction it does not possess by law (e.g., United States v. v. Mayer, 235 U.S. 55 (1914).

IV

A NUMBER OF THE PROVISIONS IN THE 1974 JUDGMENT ARE INCONSISTENT WITH THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND ARE CONTRARY TO LAW.

(1). The 1974 judgment (see pp. 5-7 supra) prohibits defendant from marketing interstate conventional diathermy devices without FDA pre-clearance of labeling. (45-54)

Such clearance is not provided for by statute or regulation.

(2). There is no provision in the Act for the recall of devices.

(3). The sweeping provisions for inspection of the premises, files and documents, with right to copy (section V(B) at 54-55 - see pp. 9-10 supra) transcend the inspection provisions of the Act, which distinguishes "devices" from food, drugs or cosmetics. (See Section 374 reproduced at pages 37-39 infra).

Since none of the defendant's activities after August or September, 1972, have been "for introduction into interstate commerce" of anything, no inspection is warranted under Section 374, and under no circumstances, under the provisions of the statute, are defendant's files, records and papers open for compulsory inspection.

Moreover, if provision for inspection was not deemed necessary or appropriate in 1972, what reason is there for such provision in 1974?

CONCLUSION

WHEREFORE, petitioner respectfully prays that a writ of certiorari issue, and for such other and further relief as the Court may deem appropriate.

Respectfully submitted,

COPAL MINTZ
Counsel for Petitioner

June 13, 1975

APPENDIX

RELATED PROVISIONS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (TITLE 21 U. S. CODE)

"§ 321 Definitions; generally. For the purposes of this chapter

* * * * *

(h) The term 'device' (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

"§331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.

* * * * *

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

BLEED THROUGH

"§332. Injunction Proceedings - Jurisdiction of courts.

(a) The district courts of the United States and the U.S. courts of the territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (h)-(j) of said section."

"§334. Seizure - Grounds and jurisdiction.

* * * * *

(d) (1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: ..."

"§352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded

(a) If its labeling is false or misleading in any particular.

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; ..."

"§374. Inspection - Right of agents to enter; scope of inspection; notice; prom[illegible] sions. [Reproduced at pages 48-50 infra.

BLEED THROUGH

inspectors of Federal Food and Drug Administration, under this section, providing that evidence obtained thereunder from person failing to permit access to and copying of records, showing movement in interstate commerce of foods or drugs received or held by him, on government officer's or employee's request, shall not be used in criminal prosecution of such person, where sections 372 and 374 of this title authorize such type of inspection, investigation and collection of samples and defendants voluntarily supplied information sought by inspectors. Id.

This section providing that records of interstate shipments of food, drugs, etc., shall be subject to inspection by government agent but that evidence thus obtained shall not be used in criminal prosecution of person from whom obtained was not applicable to suppress evidence voluntarily given government agent who made inspection pursuant to section 374 of this title authorizing factory inspection. U. S. v. Scientific Aids Co., D.C.N. J.1951, 117 F.Supp. 588.

In prosecution for having introduced misbranded drugs into interstate commerce and for misbranding drugs held and intended for shipment in interstate commerce wherein defendants moved to suppress evidence allegedly acquired by government agent in violation of defendants' constitutional and statutory rights under this section, evidence showed that defendants had voluntarily surrendered such evidence and had voluntarily made pertinent records available to government and had acquiesced in agent's examination of such records. Id.

§ 374. Inspection—Right of agents to enter; scope of inspection; notice; promptness; exclusions

(a) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions

BLEED THROUGH

subject to this chapter), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (j) or section 357(d) or (g) of this title, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Written report to owner; copy to Secretary

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been ren-

dered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Receipt for samples taken

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Analysis of samples furnished owner

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

June 25, 1938, c. 675, § 704, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, c. 350, § 1, 67 Stat. 476; Oct. 10, 1962, Pub.L. 87-781, Title II, § 201(a), (b), 76 Stat. 792.

Pertinent provision in 21 CFR:

"1.106 **Drugs and devices; directions for use**

* * * * *

(d)

* * * * *

(3) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer

OPINION AFFIRMING JUDGMENT OF 7/18/74

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 331—September Term, 1974.

(Argued March 20, 1975 Decided March 21, 1975.)

Docket No. 74-1999

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

DIAPULSE CORPORATION OF AMERICA,
also known as
the Diapulse Manufacturing Corporation of America,
a corporation,

Defendant-Appellant.

Before:

KAUFMAN, *Chief Judge,*
SMITH, *Circuit Judge,* and MACMAHON, *District Judge.**

Diapulse Corporation of America appeals from a permanent injunction issued by the United States District Court for the Eastern District of New York, John F. Dooling, *Judge*, modifying previous injunction which prohibited interstate shipment of a misbranded device known as "the Diapulse."

Affirmed.

* Of the Southern District of New York, sitting by designation.

OPINION AFFIRMING JUDGMENT OF 7/18/74

COPAL MINTZ, New York, N.Y., *for Appellant Diapulse Corporation of America.*

CYRIL HYMAN, Asst. U.S. Atty., New York, N.Y. (David G. Trager, U.S. Atty., Eastern District of New York, Paul B. Bergman, Asst. U.S. Atty., Peter Barton Hutt, Asst. General Counsel, Alvin L. Gottlieb, Deputy Asst. General Counsel, Forrest T. Patterson, Attorney, Food and Drug Division, Office of General Counsel, U.S. Dept. of Health, Education, and Welfare, of counsel), *for Appellee United States of America.*

PER CURIAM:

Diapulse Corporation of America has appealed from a permanent injunction, issued on January 18, 1974, which modified a two-year old injunction prohibiting interstate shipment of a misbranded device known as "the Diapulse."[1] We find little merit to the Corporation's claim that Judge Dooling was without authority to amend the decree rendered by Judge Rosling on July 18, 1972. *United States* v. *United Shoe Machinery Corp.*, 391 U.S. 244 (1968). The contention that the injunction was improperly extended to cover devices held by practitioners is also without merit. Such devices, used in the treatment of patients, may properly be considered "held for sale" within the meaning of the Food, Drug, and Cosmetic Act, 21 U.S.C. §331 (k). *United States* v. *Device Labeled "Cameron Spitler, Etc.",*

1 For some of the earlier history of this continuing litigation, see *United States* v. *Diapulse Manufacturing Corp.*, 269 F. Supp. 162 (D. Conn. 1967), *aff'd*, 389 F.2d 612 (2d Cir.), *cert. denied*, 392 U.S. 907 (1968); *United States* v. *Diapulse Corp. of America*, 457 F.2d 25 (2d Cir. 1972); *United States* v. *Diapulse Corp. of America*, 485 F.2d 677 (2d Cir. 1973), *cert. denied*, 94 S. Ct. 1938 (1974).

261 F. Supp. 243, 246 (D. Neb. 1966); *United States* v. *10 Cartons, Etc.*, 152 F. Supp. 360, 364-65 (W.D. Pa. 1957).

Finally, we reject the suggestion that the injunction exceeds the inspectional authority provided by the Act, by extending to all things "(including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in such place." Aside from the propriety of the provision in light of the history of non-compliance with the 1972 decree, the specification of such authority with respect to prescription drugs, added by the 1962 amendments, Drug Amendments of 1962, Pub. L. No. 87-781, Title II, §201 (a) (Oct. 10, 1962), 76 Stat. 792, was not intended "to detract from, or imply the absence of, existing authority as to other drugs or articles subject to the act." 1962 U.S. Code, Cong. & Admin. News 2889.

We find the appellant's other contentions insubstantial. Affirmed.

OPINION AFFIRMING JUDGMENT OF 7/18/74

United States Court of Appeals

FOR THE

SECOND CIRCUIT

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse in the City of New York, on the twenty-first day of March one thousand nine hundred and seventy-five.

Present:

HON. IRVING R. KAUFMAN
Chief Judge

HON. J. JOSEPH SMITH
Circuit Judge

HON. LLOYD F. MACMAHON
District Judge

United States of America,

Plaintiff-Appellee

v.

Diapulse Corporation of America, also known as The Diapulse Manufacturing Corporation of America, a corporation,

Defendant-Appellant.

74-1999

Appeal from the United States District Court for the Eastern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Eastern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order and judgement of said District Court be and they hereby are affirmed in accordance with the opinion of this court with costs to be taxed against the appellant.

A. DANIEL FUSARO,
Clerk

By VINCENT A. CARLIN,
Chief Deputy Clerk

BLEED THROUGH

POOR COPY

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

-against-

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation,

Defendant.

68 C 391

PERMANENT INJUNCTION

In accordance with the Findings of Fact and Conclusions of Law heretofore made by this Court on December 8, 1971, June 9, 1972, and May 7, 1974; after trial; it is

ORDERED, ADJUDGED, AND DECREED as follows:

I

This Court has jurisdiction over the subject matter herein and parties hereto and the Complaint for Injunction states a valid cause of action against the defendant under the Federal Food, Drug, and Cosmetic Act.

II

For the purposes of this Injunction, the following terms shall be defined as follows:

(A) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, otherwise exports permitted under 21 U.S.C. 381(d), and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body;

BLEED THROUGH

POOR COPY

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

(B) The term "device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure of any function of the body of man or other animals; the term "device" includes defined devices both in whole and in part, whether assembled or unassembled and components, parts, accessories, assemblies and subassemblies usable or adaptable to create defined devices or to convert other devices into defined devices;

(C) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any device;

(D) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any device or any of its containers or wrappers, or (2) accompanying such device;

(E) The term "prohibited device" as hereinafter used means and includes all and any of the following:

(1) Any device known as Diapulse or by any other designation, including Models D-100, D-100J, D-101, D-102, or D-103, heretofore shipped, sold, leased, or introduced or delivered for introduction into interstate commerce;

(2) Any device known as P/EmF or by any other

BLEED THROUGH

POOR COPY

designation, including any device defined in section II(E)(1) above, as modified to convert the said device to a P/EmF device;

(3) Any device consisting of an electronic instrument incorporating an electromagnetic generator which produces or is adaptable to produce pulsed, short-wave, high frequency electromagnetic energy unless; (1) the peak power available at any setting of the said device does not exceed twice the average wattage at such setting; and (2) the said device is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects from a core body temperature of 98.6°F to 104°F in 20 minutes or less at a majority of its operational settings; and (3) the said device is capable of raising the temperature of human tissue at a depth of 2 inches in the thigh muscle of living human subjects to a range of temperatures of 104°F to 113°F at a series of readily selected settings of the said device.

III

The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives, and those persons in active concert or participation with them who receive actual notice of this injunction by personal service or otherwise be and they are hereby permanently enjoined under 21 U.S.C. 332(a) from directly or indirectly causing any of the following acts with respect to any prohibited device, since such acts would result in the said device being misbranded within the meaning

BLEED THROUGH

POOR COPY

of 21 U.S.C. 352(a) and (f)(1) and would constitute violations of 21 U.S.C. 331(a) and (k):

(A) Causing to be introduced or delivered for introduction into interstate commerce any of said prohibited devices which:

(1) Bears or is accompanied by any item of written, printed, or graphic matter, including but not limited to leaflets containing directions, leaflets containing references to published medical or scientific literature, warranty brochures, advertising brochures, advertising layouts, reprints of speeches or reprints of published articles, which contain instructions for the operation, modification or alteration of any of said prohibited devices which contain statements or representations that directly or indirectly imply,represent, suggest or create the impression that any of said prohibited devices are adequate and effective in the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals;

(2) Fails to state in its labeling all of the purposes, conditions, and diseases for which any of said prohibited devices are intended for use, and for which any of said prohibited devices are represented by any means by said defendant to prospective dealers, purchasers, renters or lessees; or which fails to state in its labeling the effects of the prohibited device on the body of man or other animals;

BLEED THROUGH

POOR COPY

its mode or mechanism of action; route, methods, frequency and duration of administration; and any relevant hazards, contraindications, side effects and precautions necessary for safe use;

(3) Is intended for delivery to any person who said defendant has good cause to believe does or will represent by any means to prospective dealers, purchasers, renters, or lessees of any of said prohibited devices that said prohibited devices are adequate and effective for the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals;

(B) Causing any act to be done with respect to any of said prohibited devices while any of said prohibited devices are held for sale after shipment in interstate commerce, which act results in any of said prohibited devices being misbranded in any of the ways specified in parts (A)(1), (2) and (3) of this section: Provided, that any of said prohibited devices in the possession of any practitioner licensed by law to use or order the use of any of said prohibited devices shall be deemed to be held for sale.

IV

(A) The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives, and those persons in active concert or participation with them who receive actual notice

BLEED THROUGH

of this injunction by personal service or otherwise are hereby permanently enjoined from causing to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce any prohibited devices unless and until the said defendant assembles adequate scientific evidence on which labeling of said prohibited devices is to be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106(d), and the defendant submits such evidence and such proposed labeling to the Food and Drug Administration, Rockville, Maryland, and obtains approval thereof in writing: Provided, that where any such submission involves any device other than one defined by section II (E)(1) above, a sample of the said device shall be made available for delivery at defendant's expense to the Food and Drug Administration, Rockville, Maryland, for examination and testing.

(B) As used in this section, the term "adequate scientific evidence" means evidence consisting of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved, on the basis of which it could fairly and responsibly be concluded by such experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling or proposed labeling thereof, unless upon the

BLEED THROUGH

POOR COPY

7.

defendant's petition the Food and Drug Administration determines and advises the defendant in writing that other valid scientific evidence is sufficient to establish the effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof: Provided, that for the purposes of this paragraph the term "well-controlled investigations" shall be deemed to mean investigations conducted according to the principles specified by the regulation 21 CFR §314.111(a)(5)(ii)(a)(1)-(5) [37 F.R. 11727, March 29, 1974, recodifying 21 CFR §130.12(a)(5)(ii)(a)(1)-(5) (1973)].

(C) A shipment or other delivery for investigational or research purposes of any of said prohibited devices shall not be subject to sections III and IV(A) herein, provided that the following conditions are met:

(1) The label of each device bears the statement "For Investigational Use"; and

(2) The defendant, not less than 30 days before the proposed shipment, submits in writing to the Food and Drug Administration, Rockville, Maryland, (a) the name and address of the carrier to be utilized for the proposed shipment, (b) a full and complete description (including schematic diagram of its circuitry) of the device to be shipped, (c) the number of devices to be shipped and the serial number of each, and (d) a detailed protocol showing that the proposed

BLEED THROUGH

POOR COPY

investigation will be conducted according to the principles specified by 21 U.S.C. 355(i) in that such protocol shall include the name, address, and a complete statement of the qualifications of each investigator, the specific nature of the investigation to be conducted, the approximate number of subjects, a certification that the informed consent of all human subjects involved in the investigation will be obtained, the estimated duration of the investigation, and the intervals (not greater than 6 months) at which progress reports showing the results of the investigation will be submitted to the Food and Drug Administration.

(3) If the Food and Drug Administration determines that (a) the information submitted is incomplete, false, or misleading; (b) the device is not in fact intended to be used exclusively for investigational purposes; (c) the investigation, if conducted as proposed, would not meet the standards for adequate scientific evidence and investigations as specified by this paragraph and paragraph (B) of this section; or (d) the person (including institutional persons) undertaking the investigation is not qualified by training and experience to conduct the investigation or evaluate the effectiveness of the device, plaintiff may apply at the foot of this injunction (pursuant to Section VII) for an order specifically extending the prohibitions of this injunction to such shipment or delivery.

BLEED THROUGH

POOR COPY

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

9.

(D)(1) The defendants shall within 90 days of the date of entry of this Injunction cause the prohibited devices of Section II(E)(2) heretofore introduced or delivered for introduction into interstate commerce and all labeling accompanying said prohibited devices, heretofore introduced or delivered for introduction into interstate commerce, to be returned to the possession of the defendant by providing notice in writing to each person having possession of any of said devices advising such persons to return all such devices and labeling at defendant's expense to the defendant at its headquarters at New Hyde Park, New York, or to other suitable facilities as approved by the Food and Drug Administration; a copy of said notice to be transmitted to the Food and Drug Administration, Rockville, Maryland, on the date such notice is first transmitted to the person having possession of said devices.

(2) For the purpose of accounting for the returned labeling, for each of the said returned devices, and for each of the said prohibited devices which cannot be returned by reason of previous destruction or because it is in the custody of a United States District Court, or is otherwise unavailable, the said defendant shall within 120 days of the date of entry of this Injunction submit to the Food and Drug Administration Rockville, Maryland, separate listings in writing as follows:

BLEED THROUGH

POOR COPY

(a) for each of said returned devices, the model number, serial number, and, the location to which returned; (b) for each of said devices unavailable to be returned, the model number, serial number, and the reason for its unavailability; (c) for accompanying labeling, the location to which returned.

(3)(a) The defendant shall, within 180 days of its compliance with the provisions of paragraphs (D)(1) and (2) of this section, determine whether to attempt to bring the said returned devices into compliance with the law by relabeling or modification pursuant to the provisions of paragraph (A) of this section or whether to destroy or salvage (for other than device purposes) the said returned devices, and within said 180 days (or within such additional time as authorized by the Food and Drug Administration) the defendant shall give written notice to the Food and Drug Administration, Rockville, Maryland, that defendant is prepared to bring the returned devices into compliance with the law or to effect their destruction or salvaging (for other than device purposes) under the supervision of a duly authorized representative of the Food and Drug Administration: Provided, that the defendant shall not commence such compliance or destruction or salvaging operations until it has received authorization in writing to do so from the Food and Drug Administration, Rockville, Maryland.

(b) The defendant shall under no circumstances whatsoever ship, sell, offer for sale, or otherwise dispose of any part of said returned devices until duly authorized

BLEED THROUGH

POOR COPY

11.

representatives of the Food and Drug Administration shall have had free access thereto in order to make any examination or inspections that are deemed necessary, and shall in writing have released said devices for shipment, sale, or other disposition.

V

The defendant, Diapulse Corporation of America, a corporation, shall:

(A) Submit to the Food and Drug Administration, Rockville, Maryland, within 10 days of the date of entry of this Injunction, a written list stating the complete street address, including post office zip code, of each of the offices, plants, factories, warehouses, storage facilities, or other establishments used by the said defendant for the manufacturing, assembling, processing, packing, transporting, or holding of any device or which is used by the said defendant to hold any equipment, finished and unfinished materials, containers, labeling, records, files or other papers bearing on the manufacturing, assembling, processing, packing, transporting, or holding of any devices; and shall thereafter submit notice in writing to the Food and Drug Administration, Rockville, Maryland, as to each disposition or acquisition of such establishments within 10 days of each such occurrence.

(B) Grant duly authorized officers and employees of the Food and Drug Administration free access to any of its offices, plants, factories, warehouses, storage facilities, or other

BLEED THROUGH

POOR COPY

establishments at reasonable times during regular working hours, within reasonable limits and in a reasonable manner to inspect such establishment and all pertinent equipment, finished and unfinished materials, containers, and labeling therein; and such inspection may include copying and photographing and shall also extend to all things therein (including records, files, papers, processes and facilities) bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed, transported, or held in such place.

VI

The defendant shall give notice in writing of this Court's decision of May 7, 1974, by submitting within 30 days of the date of the entry of this Injunction a form of notice to the Food and Drug Administration, Rockville, Maryland, for approval in writing, and within 30 days of receiving such approval, shall send by receipted mail a copy of such notice and a copy of this Injunction to each person known to the defendant to have purchased or leased, or to have in his possession any of said prohibited devices, and shall send by certified mail, return receipt requested, a copy of such notice and a copy of this Injunction to each of the officers, agents, and employees of the defendant or of any subsidiaries owned in whole or in part by the defendant, and to each person who has been or is a distributor of any of said prohibited

BLEED THROUGH

POOR COPY

devices or a sales representative for any of said devices, and to all persons now in active concert or participation with said defendant, assisting or participating in the sale, promotion, or manufacture of said devices, and to all persons who have been or are now engaged in testing or research involving any of said prohibited devices; and defendant within 40 days from the date of entry of this Injunction, shall advise in writing the United States Attorney, Eastern District of New York, Brooklyn, New York, of the name and address of each person so notified; and defendant shall supply a copy of said notice and a copy of this Permanent Injunction to all persons in the future in active concert or participation with said defendant, assisting or participating in the sale, promotion, or manufacture of said devices, and to all persons known to the defendant to be engaged in testing or research involving any of said prohibited devices.

VII

This Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate.

VIII

The plaintiff, United States of America, shall recover

BLEED THROUGH

POOR COPY

PERMANENT INJUNCTION, DOOLING, J.,
DATED 7/17/74 FILED 7/18/74

from the defendant, the costs of this action, to be taxed by the Clerk of the Court.

Brooklyn, New York

July 17, 1974.

APPROVED

U. S. D. J.

CLERK

PERMANENT INJUNCTION -- JULY 18, 1972

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FILED
in Clerk's Office
U.S. District Court E.D. N.Y.

UNITED STATES OF AMERICA,

Plaintiff,

Civil No. 63-C-391

v.

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation,

Defendant.

PERMANENT INJUNCTION

In accordance with the Findings of Fact and Conclusions of Law heretofore made by this Court on December 8, 1971, and June 9, 1972, after trial, it is

ORDERED, ADJUDGED, AND DECREED as follows:

I.

This Court has jurisdiction over the subject matter herein and parties hereto, and the Complaint for Injunction states a valid cause of action against the defendant under the Federal Food, Drug, and Cosmetic Act.

II.

The Diapulse device referred to in this Injunction is an electromagnetic generator similar to conventional medical diathermy but differing from it in that its output is pulsed and in that it lacks the energy output of conventional medical diathermy. The Diapulse is classified as a dia-

BLEED THROUGH

POOR COPY

thermy device under the regulations of the Federal Communnications Commission and operates on the 27.12 megacycle wave length authorized by the FCC for diathermy devices.

III.

The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives, and all and any persons in active concert or participation with it be and they are hereby permanently enjoined under 21 U.S.C. 332(a) from violating 21 U.S.C. 331(a) and (k) by directly or indirectly causing any of the following acts with respect to articles of device known as Diapulse, or any similar articles of device, since such acts would result in the device being misbranded within the meaning of 21 U.S.C. 352(a) and (f)(1):

A. Causing to be introduced or delivered for introduction into interstate commerce any of said articles in whole or in part, assembled or unassembled, which:

1. Bears or is accompanied by any item of written, printed, and graphic matter, such as leaflets containing directions for use, leaflets containing instructions, and warranty brochures, advertising brochures, advertising lay-outs, reprints of speeches, and reprints of published articles, which contain statements and representations that directly or indirectly infer, represent, suggest, or create the impression that said articles are adequate and effective in the cure, mitigation, treatment, or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals.

2. Fails to state in its labeling all of the purposes, conditions, and diseases for which said articles are intended for use, and for which

BLEED THROUGH

POOR COPY

said articles are represented by any means by said defendant to prospective dealers, purchasers, renters or lessees; and which also fails to state in its labeling the effects of the device on the human body, its mode or mechanism of action; route, methods, frequency and duration of administration; and any relevant hazards, contraindications, side effects and procautions necessary for safe use.

3. Is intended for delivery to any person whom said defendant has good cause to believe does or will represent by any means to prospective dealers, purchasers, renters, or lessees of said articles that said articles are adequate and effective for the cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals.

B. Causing any act to be done with respect to any of said articles while any of said articles are held for sale after shipment in interstate commerce, which act results in any of such articles being misbranded in any of the ways specified in parts 1, 2, and 3 of paragraph A above.

IV.

The defendant, Diapulse Corporation of America, a corporation, and each and all of its officers, agents, servants, employees, and representatives and all and any persons in active concert or participation with it be and they are hereby permanently enjoined from causing to be shipped, sold, leased, introduced or delivered for introduction into interstate commerce, or otherwise disposed of, any of said articles of device known as Diapulse, or any similar articles of device, in whole or in part, assembled or unassembled, unless and until the said defendant assembles the scientific evidence on which labeling of the device is to

BLEED THROUGH

POOR COPY

be based, the defendant prepares the labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 CFR 1.106, and the defendant submits such evidence and labeling to the Food and Drug Administration and obtains approval thereof in writing.

V.

The defendant, within 30 days from the date of entry of this decree, shall give written notice by certified mail, return receipt requested, of the provisions of the judgment of this Court by sending a copy of the Court's memorandum decision of June 9, 1972, and a copy of this Permanent Injunction, to each and every person known to the defendant to have purchased, leased or have in his possession a Diapulse device, and to the officers, agents, and employees of the defendant and to each and every person who has been or is a distributor of the Diapulse device or a sales representative for said device, and to all persons now in active concert or participation with said defendant, assisting or participating in the sale, promotion, or manufacture of said device, and defendant within 40 days from the date of entry of this Permanent Injunction, shall advise plaintiff of the name and address of each person so notified, and defendant shall give said notice of the provisions of this Court's judgment to all persons in the future in active concert or participation with said defendant, assisting and participating in the sale, promotion, or manufacture of said device or any similar device.

BLEED THROUGH

POOR COPY

PERMANENT INJUNCTION--7/18/72

VI.

The Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate.

VII.

The plaintiff, United States of America, shall recover from defendant the costs of this action, to be taxed by the Clerk of the Court.

DATED: Brooklyn, New York

July 15, , 1972.

/s/ George Rosling
UNITED STATES DISTRICT JUDGE

BLEED THROUGH

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

U.S. DISTRICT COURT
MAY 7 1974
TIME A.M.

UNITED STATES OF AMERICA,

- against -

DIAPULSE CORPORATION OF AMERICA, et al.,

Defendants.

73 CR 973

68 C 391

MEMORANDUM INCORPORATING FINDINGS of FACT and ORDER

Appearances:

CYRIL HYMAN, Esq., and FORREST PATTERSON, Esq., (EDWARD JOHN BOYD V., Esq., United States Attorney, of Counsel)
For the Government

COPAL MINTZ, Esq.
For Defendants

DOOLING, D. J.

The present proceeding was initiated by an Order to Show Cause of August 1, 1973 (filed August 3, 1973) why Diapulse Corporation of America, DCA Leasing Corp., Jesse Ross and Bernard O. Siler, should not be punished for contempt for disobeying the preliminary injunction in the civil action (which had been affirmed by the Court of Appeals) by sending from New Hyde Park to Las Vegas, consigned to Jesse Ross, President of Diapulse and of DCA, an article of device labeled P/EmF and for violating the final injunction entered July 15, 1972, by sending to Robert Zimmerman of Zimmerman Medical Equipment, Inc., and Doctors Coordinate, Ltd., on July 19, and on July 25, from New Hyde Park to Pecatonica, Illinois, P/EmF Modification Kits; by sending to Melvin C. Appel of Professional Electronics, Inc., in Portland, Oregon from New Hyde Park, such a P/EmF

BLEED THROUGH

POOR COPY

Modification Kit; by sending to Gilbert Cook (Gil Cook X-Ray Co.) in Tampa, Florida such a P/EmF Modification Kit; and by sending on or about August 2, 1972 to Joseph R. Groves of Medical Equipment Company in Roanoke, Virginia from New Hyde Park, several P/EmF Modification Kits; and by sending literature respecting Diapulse from New Hyde Park to Campbell Soup Co. in Chicago, Illinois, while Campbell Soup had in its possession a Diapulse article of device.

There is no genuine controversy about what the defendant Diapulse and the individual defendants and DCA did. The P/EmF labeled device was, of course, sent from New Hyde Park to Las Vegas for display at a convention or conference of the American Physical Therapy Association; it was sent after the preliminary injunction had been affirmed in the early part of June 1972, and it was returned to New Hyde Park after the convention ended in June 1972, both shipments being made while the preliminary injunction was in full force and effect and before the final injunction had been entered. The preliminary injunction forbade the introduction into Interstate Commerce of "any of said Diapulse devices, assembled or unassembled" and "Diapulse Devices" are inferentially defined as those "substantially identical" with the Diapulse Device, the propriety of the seizure of which by the government was adjudicated in the earlier Connecticut action. See 269 F.Supp. [illegible], 389 F.2d 612, certiorari denied, 392 U.S. 907.

After the issuance of the final injunction defendant

BLEED THROUGH

POOR COPY

DCA Leasing Corp., a wholly owned subsidiary of Diapulse, having common officers and control, shipped 297 of the P/EmF Modification Kits to purchasers within the United States. Fifty-five of these were shipped to Ross Medical Electronics in Kensington, Connecticut; 41 to Medical Aid Sales Company in Brooklyn, New York; 36 to Doctors Coordinates in Pecatonica, Illinois (Robert Zimmerman); 30 to Robert Ford in El Monte, California; 24 to Melvin Appel (Professional Electronics, Inc.) in Portland, Oregon, and 20 to Gilbert Cook at Gil Cook X-ray Company in Tampa, Florida, with smaller numbers being shipped to buyers in other locations. In addition, the Diapulse Corp. has shipped to foreign countries since the date of entry of the final injunction, Diapulse equipment of the kind sold in the United States before the litigation in Connecticut and in New York.

The principal models of Diapulse equipment that had been manufactured and distributed before the litigation were identified as D-101, of which 2400 to 2500 had been made and sold, for the most part in the United States, and the D-102, 2000 to 2500 of which were made and sold principally in the United States. Roughly 700 of Diapulse devices in all have been made here and sold abroad.

The Diapulse device condemned in the Connecticut case and dealt with in the temporary and permanent injunctions in this Court is classified for Federal Communications Commission type-approval purposes with diathermy devices. It

BLEED THROUGH

POOR COPY

is a short wave, high frequency, electromagnetic device operating at 27.12 megahertz, and is operable from a standard 117 volt 60 cycle AC 5-1/2 ampere electric current, the kind delivered by American utilities to residential and commercial properties.

Characteristic of the Diapulse device is that its electromagnetic energy is pulsed, that is, delivered in very short bursts of electrical energy separated by rather wide spaces in which no electromagnetic energy is flowing. The pulse width or pulse duration in the Diapulse device was 65 millionths of a second. That was an unalterable feature of the equipment: that at all pulse frequencies the length of the individual pulse was the same 65 millionths of a second. The Diapulse device had six pulse frequency settings, that is, 80 pulses per second, 160 pulses per second and then 300, 400, 500 and 600 pulses per second. Simple multiplication demonstrates that the effect of that is that when 80 pulses per second were used, each pulse being 65 millionths of a second in duration, the current was actually flowing approximately one-half of 1% of the time, that is, 0.52%. In consequence, at 160 pulses per second the current would be flowing about 1% of the time, at 300 pulses a second the current would be flowing 1.9% of the time and so on up to 600 pulses per second when the current would be flowing for 3.9% of the time.

In the Diapulse device of the past, peak power expressed in watts during each short burst of power was 975

BLEED THROUGH

watts. There were on the Diapulse of the past six power settings; on the machine's control panel power settings were treated as "penetration" levels, since it was the teaching of the authors of the machine that peak power determined the penetration of the electromagnetic effect into the body. The six peak power settings were at 293 watts, 390 watts, 488 watts, 585 watts, 780 watts and 975 watts. Since, as noted, the device deliveredcurrent for as little as one-half of 1% of the time at 80 pulses per second and at 3.9% of the time at 600 pulses a second, the average power output was radically lower than the peak power. Indeed, at the lowest penetration setting and the lowest pulse frequency setting the average watts of output power was 1.52 watts; at the highest penetration and pulse rate settings the output was 38 watts.

The electromagnetic energy emanating from the device was delivered to the person under treatment through an applicator or treatment head roughly the shape of a kettle drum; the operative part of the treatment head was an induction coil comprising a number of concentric turns of heavy, banded conductor. The treatment head functioned by inducing a flow of current in the tissues at depth; that is, the device operated by induction. The Diapulse device inevitably produced heat at depth, but not in any therapeutically significant amount; indeed, the only indication is that at its highest settings at the end of 20 minutes it could result in an increase in local tissue temperature from normal to 101-1/2°F.

BLEED THROUGH

POOR COPY

6

The Diapulse device was over the years presented aggressively as an electromagnetic therapeutic device. It was, explicitly, not for heat therapy. On the contrary, it was for electromagnetic therapy, and was originally presented as essentially athermal, and it was only reluctantly conceded that it produced some local increase in temperature within the human tissue at depth, the extent of any such increase in temperature being a function of the capacity of the circulation of body fluids in the tissues to attemperate the inevitable evolution of heat by the flow of electromagnetic energy in the tissue. Defendants have not accepted the view that any physiological effects claimed for Diapulse treatment are due to the mild elevation in temperature inseparable from any application of electromagnetic energy to human tissue through a machine with the characteristics of the Diapulse. Defendant Ross, speaking for the companies and himself, was explicit that the interest of the group is not in diathermy nor in diathermic therapy as such, nor, indeed, in diathermic modalities. The insistence of defendant Ross and the corporations for which he speaks continues to be on the validity and utility of the use of pulsed short-wave, high peak-power, electromagnetic induction as a therapeutic agent, and their long-term interest is in the manufacture or assembly and distribution of medical modalities capable of administering such therapy.

BLEED THROUGH

POOR COPY

Defendants have continued to encourage and, to an extent not disclosed, to lend support to a large number of research projects, clinical and other, here and abroad; the evidence requires the conclusion that all of these, without exception, are devoted to exploring the physiological effect and therapeutic utility of pulsed electromagnetic therapy of the kind which the Diapulse devices D-101 and D-102 are capable of supplying and are limited to supplying, and that there are no research projects of any kind devoted to diathermic heat therapy which have the support or sponsorship or claim the interest of defendants.

It appears that the Diapulse device as recently as at the time of the Las Vegas convention referred to above, was offered for sale in the range of $2,200.00 for each Diapulse modality.

Critically important findings were made by Judge Rosling at the time of the issuance of the preliminary injunction under date of December 18, 1971, and these findings were the following:

> "15. The Diapulse device is claimed to be a pulsed electromagnetic generator which resembles a conventional medical diathermy unit but lacks the energy output of conventional medical diathermy units. It emits its energy in bursts exceeding at such points of emission the output of such conventional unit, and maintains periods of reduced emission or complete lack of emission during intervals between the bursts. The further claim by defendant is that during the period of reduced output the heat generated by the bursts is dissipated, that therapeutic effect is achieved by the penetration

BLEED THROUGH

POOR COPY

"of the electromagnetic field of the device into the human body, and that the non-production of heat in consequence of the operation and application of the device to the human body eliminates the possibility of injury to the body from excess heat generated.

The device, has, however, been classified as a diathermy unit by the Food and Drug Administration, permitted to operate, and in fact operating on a wave length authorized for comparable diathermy devices, namely, 27.12 megacycles, and deriving its therapeutic value, if any, from the introduction of penetrating heat into the human body.

The determination of the Connecticut suit adjudicated the issue respecting the functioning of the Diapulse device in favor of the Food and Drug Administration, and the additional testimony adduced before this court served merely to show that there were some dissenting views of witnesses based on inconclusive results grounded on inadequate data and conjectures drawn therefrom, with a strong suggestion, at least, that some of the witnesses were pseudoexperts who had been financially corrupted by defendant by cash payments or stock interests in defendant or had had their conclusions colored by a heavy investment in the device which proved economically profitable in the practice of the medical or dental professions.

16. In the interstate sale and distribution of the device defendant has utilized a great many items of written, printed and graphic matter which comprise the labeling of the Diapulse device, including leaflets containing directions for use, instructions, warranty and advertising brochures and advertising layouts, reprints of speeches, and reprints or excerpts of reports and published articles concerning the Diapulse device or implying, by association of the name Diapulse with other matter in said documentation, or ambiguously, that there was a relationship

"between the functioning and value of the device and therapeutic claims asserted in the article or report.

17. In the promotion of the interstate sale and distribution of said Diapulse device, the defendant has organized symposia, sponsored meetings and has had exhibits and sales representatives at meetings of physicians, dentists, and other practitioners or alleged practitioners of the healing arts to whom representations were made by or in behalf of the defendant orally and by labeling as to the mode and mechanism of action of the said Diapulse device and its effectiveness in the treatment of disease and in affecting the functions and structure of the human body.

18. The jury, in the Connecticut forfeiture case against the device, reported in addition to its general verdict of misbranding that the Diapulse device there in controversy was misbranded and misrepresented with respect to its therapeutic value in the treatment of 49 diseases, disorders, and conditions and that false or misleading claims had been made in that regard. Pursuant to the charge of the court that it should select only some of the more significant claims as to which interrogatories were propounded by the court and report on them alone as to their falsity and misleading nature, the jury had left 68 interrogatories unanswered.

The 49 affirmative findings became in consequence res adjudicata and are binding upon this court. Upon close examination, however, of the list of 49 interrogatories thus answered, it is apparent that their scope is so broad that they should be construed as including in their sweep practically all disorders and conditions which afflict the human body or to which it is subject. This conclusion is understandable, for the list is not a scientific one which the Government with the assistance of qualified medical experts prepared, and hence one which should be free of overlapping or undue vagueness in its glossary."

BLEED THROUGH

POOR COPY

19

The findings made in the decision of December 8, 1971, were reincorporated in the Court's decision granting the final injunction dated June 9, 1972, and filed June 12, 1972. One further finding made in the preliminary injunction decision and carried forward to the date of the final injunction is the following:

> "A panoptic view of the proof before this court persuades it (1) that defendant in the sale or other disposition of the device continues to make claims respecting its therapeutic value which were adjudicated false in the Connecticut suit; (2) that defendant has failed and continues to fail to disclose in its literature that there is at least a very substantial body of medical and scientific opinion which is in complete disagreement with the claims made by defendant concerning the therapeutic efficacy of the Diapulse device; (3) that it has not discontinued its substantial sales, leasing, and other disposition of the device in interstate commerce; (4) that no proof on defendant's part is in prospect which may reasonably, when and if introduced, be expected to alter the court's findings as herein set forth; (5) that this court is not a pharmaceutical house with expertise to delineate the outer limits of claims of therapeutic value of the device and the scientific basis for such claims with the exactitude required in a complex judgment unless it is aided by the processing of the device by the Food and Drug Administration; (6) nor is it, until these claims have been thus delineated and evaluated by said body, in a position to give directions for publicity by the defendant which will not only inform the public as to what, if anything, the machine is capable of, but will have the effect of enlightening the public as to the generally held views of science to the contrary of the company's claims and of cancelling out the influence, based on misbranding and misrepresentation, of literature heretofore circulated by defendant."

BLEED THROUGH

POOR COPY

The circuitry of the Diapulse D-101 and Diapulse D-102 is shown in Exhibit 30 at pages 12-13 (for Model D-101) and in Exhibit 32 (the centerfold pages, 12-13). In each of these schematic circuit portrayals, in the upper panel, labeled RF-CHASSIS, the portion on page 12 of Exhibit 30, and the left hand page of the centerfold page in Exhibit 32, there is a capacitor marked "C41", which appears very near the bottom of the upper panel of the two panel drawing below the assembly marked "Multivibrator". That capacitor is identified as a 5600 pf multivibrator feedback capacitor. It is directly related to the pulse frequency range of the Diapulse 101 and 102 modalities. See Exhibit 30 at page 24, part No. BP2352; Exhibit 32, page 23, part No. BP2352.

As noted above, the treatment head of the Diapulse device is in effect an induction coil and the inner diameter of the coil is in the order of five inches. Yet it is used both for local application, as for example in treatment of otitis media, and for a wholly different kind of application: that is, application over the liver and adrenal glandular regions where it is claimed to function to stimulate body systems broadly, and by such stimulative reinforcement of natural curative processes of the body, to ameliorate conditions affecting remote parts of the body, including the toes.

While the government has seized a number of Diapulse units for condemnation from the possession of practitioners, where used, after shipment in interstate commerce, in

BLEED THROUGH

POOR COPY

allegedly therapeutic treatment of disease conditions, by far the greater number of the Diapulse machines sold and delivered in this country remain in the hands of the institutions and practitioners, including chiropractors and masseurs as well as medical doctors and physical therapists, who used them as therapeutic devices before the injunctions in the present case. Although there is no contention that defendants have failed to comply with the mailing and notice requirements of Paragraph V of the permanent injunction, the evidence indicates that the possessors of the devices still have in their possession the Diapulse literature with its elaborate teachings of the electromagnetic therapeutic treatment.

Before the entry of the final decree in the present case and as early substantially as the date of the rendition of the final decision in the present case, defendants evolved the concept of the P/EmF. That concept was to provide a relatively inexpensive means of converting the Diapulse machine to a machine to be called P/EmF which would have an "extended range" of application in the sense that it would have an additional range of pulse frequencies extending from about 600 pulses per second to approximately 2800 pulses per second and would have an increase in maximum peak power from 945 to 2153 watts. The converted device would, in all of its principal operating parts, including the treatment head, be the Diapulse device. It would continue to be a pulsed

BLEED THROUGH

13

electromagnetic modality operating with short wave high frequency at 27.12 megahertz, using an input voltage of 117 volts at 60 cycles alternating current and 5-1/2 amperes. The duration of each pulse would as before be 65 millionths of a second at every pulse-frequency level. The difference would be the introduction of a higher power range, between 945 watts and 2153 watts and the higher pulse frequency range from a top frequency of 600 pulses per second to a top frequency of approximately 2800 pulses per second. The extended range of pulse frequency would, however, to some extent be offset by a compensating reduction in the available peak power, the highest peak power being available only at the lowest pulse frequency setting and the lowest peak power being available at the highest pulse setting only. The annexed Tables A and B show the contrasting peak power, average power, pulse frequency and "duty cycles" of the two devices.

The P/EmF conversion kit included a "relay" and a relay mounting socket and an example of these is contained in Exhibit 21: the "relay" is the device enclosed in the clear plastic enclosure, and the "mounting socket" with the tabs numbered at the base of each tab on the mounting socket is the white plastic body that mates with the prongs and screw at the base of the relay. Also included in the kit was a 750 PF capacitor, and this is identifiable in Exhibit 21 as the

BLEED THROUGH

POOR COPY

small yellow pill-like disc with two wires extending from it which is marked "X5F, RMC, JL750, 10%". With each modification kit DCA Leasing Corporation sent to the consignee a letter enclosing a sheaf of papers typified by Exhibits 25 (addressed to Gilbert Cook), Exhibit 41 (addressed to Melvin C. Appel, Professional Electronics, Inc.), Exhibit 61 (shipped to Zimmerman and by his organization given to Gerald M. Rodgers at the time his Diapulse machine was exchanged for a P/EmF machine in July of 1972), and Exhibit 31, first pages (as obtained by FDA). Among the pages included in the sheaf in each case is one page entitled "EXTENDED RANGE FOR RF CHASSIS MODIFICATION PROCEDURE" and Paragraphs numbered 4, 5 and 6 on this page of instructions cover the single critical change in the entire modification kit approach. With the aid of "RF Chassis Component Location" sheets 5 and 7 and other sheets, it will be seen that the capacitor C41 is cut out of its old location and is tranferred to two terminals of the newly installed relay socket and relay, and that the new 750 PF Capacitor is installed, between two of the other terminals on the relay socket (the terminal lugs used are 2, 3, 6 and 7). The new relay makes it possible either to switch the 5600 PF capacitor into the circuit, retaining the capability to control the pulse repetition frequency from 80 to 600 pulses, or alternatively to switch the new 750 PF capacitor into the circuit, making available a range of pulse frequencies

BLEED THROUGH

POOR COPY

from around 600 to approximately 2800 pulses per second. Both capacitors are stock items obtainable in commercial electronic supply sources. The rest of the materials in the kit have subsidiary and somewhat mechanical roles connected with the elimination of the watt meter that appeared at the left of the Diapulse panel and which was parasitic and not integral to the circuitry of the Diapulse machine, the installation of the switch at the far left of the panel for switching between the two pathways furnished by the relay between the 750 PF path and the 5600 PF path, and accompanying panel lights to show which path was in use, etc. While the peak power of the device was materially increased, [redacted] from 975 watts to 2153 watts, that change did not require the introduction of any new major component, or the substitution of any new component for an old major component.

The evidence concerning the operating characteristics of the Diapulse as modified, when used in the range of 80 to 600 pulsations per second, is not altogether satisfactory; however, the preponderance of evidence is that use of the modification kits as sent out in June, July and the first part of August 1972, in accordance with the accompanying instructions, gave the modified Diapulse devices a design output, as P/EmF devices, when operating at 80 to 600 pulse frequency, identical with that of the Diapulse D-101 and D-102. At the higher range of around 600 to around 2800 pulsations

BLEED THROUGH
POOR COPY

per second, (except in the case of the Appel device which was deliberately retuned to substitute an 80 millionths of a second pulse length) the peak average wattage at highest setting would be in approximately the range of 90 watts. The device tested at the Federal Communications Commission was a little higher in pulse frequencies at each setting. It had come from Gilbert Cook in Tampa and was modified from a Diapulse under the direction of Robert E. Byrum. The "P/EmF" as thus produced in accordance with the installation instructions sent out by DCA Leasing Corporation duplicated in every particular the capability of a Diapulse device of the D-101 and D-102 kinds. Any possessor of a P/EmF device produced through the use of the modification kit to modify a Diapulse D-101 or D-102 who had theretofore used a Diapulse device for experimentation, test, or as a therapeutic instrument, could use the P/EmF device exactly as he had used the Diapulse device without any change whatever in procedures. If he did not use the 7-12 range that made available pulse frequencies from 600 to 2800 pulses per second, there was no difference whatever in the utility and capability of the machine. Use of the P/EmF in the setting 7-12, 600 to 2300 pulses per second, range increased average wattage from the peak of about 38 watts in the lower, 6-12 range to a peak of 90 or 100 watts at the higher settings, 7-12, of the device. Nothing in any of the literature sent out with the modification kits for use in connection with the Diapulse devices as modified distinguished any point at which a difference in operating characteristics

BLEED THROUGH

from the older Diapulse machine took effect, and nothing in any of the literature made any specific recommendation about the settings at which treatment for the various conditions said to be treatable by the device should be treated. The only guide suggested was the patient's response to a sensation of increased temperature. To a convinced user of Diapulse, in consequence, the effect of the modification would simply be to enable him to resume treatment just as before with the unmodified Diapulse under the impression that he had, possibly, now in his possession a device which had not been disapproved by the FDA or by any Court.

The four page P/EmF brochure distributed with the modification kits is phrased exclusively in terms of heat treatment through use of high frequency diathermic currents locally applied to heat superficial and deep tissues. However, while noting that, "The beneficial effects of diathermy are derived solely on the basis of heat produced," the brochure makes it plain -- in a legend just under the table of physical conditions for which the apparatus may be used -- that the converted unit will produce only enough heat to raise the temperature of deep muscle tissue 2 inches below the surface of the mid-thigh from 98.6°F to 104°F in an average time of less than 15 minutes with the switch in "up" position and both the penetration and pulse frequency dialed to their highest settings of 12 and 6. That is, the users of the Diapulse device (and the modification kits were necessarily addressed exclusively to owners and users of existing

40

Diapulse machines) were at once warned that the heat effect, the diathermic effect, was characteristic only of the extended range introduced at pulse frequencies from 600 to 2800, and that the device delivered the characteristic Diapulse treatments as illustrated in Exhibits 50, 51 and 52, issued in 1968 and 1969, unless the new switch was flipped up, through use of the device at 80 to 600 pulses per second.

The Diapulse brochures of 1968 and 1969, Exhibits 50, 51 and 52, emphasize the idea that clinical and experimental studies showed that many of the effects of high frequency energy "are due to electromagnetic effects other than heat. DIAPULSE was developed to take advantage of this important finding, and to increase the range of application of this valuable new form of therapy." (See Exhibit 52.) The same brochure emphasized that the time lapse between electromagnetic impulses gave "ample time for dissipation of any heat which may be produced by the energy burst" permitting deep penetration of high intensity "with no significant rise in temperature, either locally or systemically." The brochure asserts that when applied over the epigastric area (roughly frontally at the approximate top of the abdomen, see Exhibit 50) "DIAPULSE therapy is capable of increasing peripheral blood flow without hyperpyrexia" (Exhibit 52). Similarly, Exhibit 51 of 1968 emphasized the Diapulse as emitting "pulsations of high intensity electromagnetic energy designed to accelerate natural healing without danger of hyperpyrexia or overheating of tissue," permitting "deep penetration without any significant increase in temperature either locally or systemically."

BLEED THROUGH

The brochure accompanying P/EmF suggested nine therapeutic uses of the modified device. Three of these had affirmatively been found by the jury in the Connecticut case to be false or misleading representations contributing to the finding of misbranding. The P/EmF brochure lists osteoarthritis as one condition for which "diathermy is useful" and osteoarthritis was a condition for which the jury found that a false claim was made for Diapulse. The P/EmF brochure lists "peripheral vascular disease" and states that for patients having an occlusive arterial disease it might be advisable to apply diathermy to the upper portion of the thighs, etc. The Connecticut jury had found the Diapulse falsely or misleadingly branded in claiming efficaciousness for treatment of occlusive vascular disease and peripheral vascular insufficiency. The P/EmF brochure lists otitis media as an infection for which patients could occasionally obtain relief by heat applications. The Connecticut jury had found the Diapulse device also misleading in its claim to relieve otitis media and ear conditions.

Reference to the charge in the Connecticut case, to the exceptions taken to the charge, and to the request for supplementary charge show that the jury's responses to the question whether false or misleading statements were made with respect to some 121 different conditions were given in the

BLEED THROUGH

POOR COPY

understanding that a general verdict of misbranding would be found if even one misleading or false statement was included in the broadly defined "labeling" of the seized Diapulse device. The Court did not require the jury to pass on all 121 listed ailments or conditions; the Court requested the jury to answer "yes" as to those ailments or conditions about which the jury was unanimous in finding that a false or misleading claim had been made. The Court explicitly refused to have the jury write the word "no" next to those conditions which in their unanimous opinion were not misrepresented, that is, conditions about which efficacy-claims were made, and the claims were neither false nor misleading. Hence, the jury's verdict affirmatively and unanimously finds that Diapulse had been falsely or misleadingly represented as therapeutically useful for each of the 49 particular ailments or conditions as to which it answered, "yes". It made no finding that the device had any therapeutic utility as to any of the ailments or conditions left blank.

The jury was authorized to find that a claim was false or misleading if it found (a) that a particular claim of therapeutic utility was the subject of a difference of opinion among experts qualified to have an opinion by their scientific training and experience and (b) that the label failed to disclose the existence of that difference in opinions. As the Court put it (Tr. 2726-2727)

BLEED THROUGH

POOR COPY

> "Now, the failure to disclose the existence of an honest difference of opinion, as I say, might make the opinion expressed in the labelling misleading because you haven't told about the other difference of opinion; but this other difference of opinion, in order to affect the label, should be a material weight of opinion contrary to what the label says. . . . if you should find that there were any significant studies unfavorable to Diapulse and if you should find that the Diapulse Corporation knew of these studies or should have known of them and didn't publish them or distribute them as part of the labelling, then on that ground alone, the labelling was misleading because only half a story is told."

The brochure accompanying P/EmF contained at its third page following the listing of the "Operating Procedures" a note to procedure No. 3, and its reference to settings 1 through 6 of the pulse frequency dial. That note read:

> "Note: The F.D.A. and many medical authorities are of the opinion that these lower settings are medically useless."

While there is definite and credible evidence that dealers were instructed in connection with the distribution of P/EmF to take up old Diapulse literature from users of Diapulse machines when the P/EmF modification kits were used to convert their machines or their machines were exchanged for converted machines, there is evidence that one dealer at least failed to do this in at least one case, and there is little evidence that the instructions were practical or were or could be carried out systematically. It is moreover manifest that since the Diapulse machine had been distributed in large numbers for a number of years before the adverse finding in the

BLEED THROUGH

Connecticut case and a flow of literature to Diapulse users was kept up at least into 1969, the mildly unobtrusive footnote about FDA and medical authority opinion, and the statements about the therapeutic use of heat-diathermy can hardly be supposed adequate to efface the effect of defendants' systematic indoctrination of Diapulse "therapists" with the thermal electromagnetic therapy concept, particularly in view of the practitioners' stake in continuing the use of his therapeutic method and modality without change.

Moreover the facts do not warrant putting the P/EmF forward as a diathermic heat-treatment device.

The evidence is that before the introduction of Diapulse there were no pulsed diathermic machines used therapeutically for diathermic heat therapy. After the introduction of Diapulse one or several pulsed diathermic heat-treatment devices did appear, but they remained exceptional and not in the main stream of conventional diathermic heat treatment devices. In very general terms, diathermic heat therapy devices operate in the range of 100-400 average watts and, in general, aim at increasing tissue temperatures at depth to the range of 104° to 113.9°F. The Federal Communications Commission has issued something like 300 type-approvals for diathermic devices with power capabilities in the range of 0-7 watts to 600 watts.

Specialists in Physical Medicine and Rehabilitation recognize two basic types of heating devices used in heat

BLEED THROUGH

POOR COPY

therapy: that is, superficial heating devices such as hot pads, electric heating pads, heat lamps, hot water or paraffin applications; and deep heating devices, including such devices as short-wave diathermy devices, microwave diathermy devices, and ultra-sound devices. The term "diathermic devices" means devices used as a means of heating tissue deep in the body where heat is the indicated therapy. Short-wave and microwave diathermy alike are radio transmitted and produce heat in body tissue by induction: they induce a flow of current in the body and tissue resistance to the flow of the current evolves heat. Ultra-sound utilizes sound wave, and the resistance (or impedance) to the propagation of the sound wave in the tissue converts the sound energy into tissue heat.

The evidence at the trial before Judge Rosling was that diathermy was recognized as having specific physiological capabilities including: relief of spasm; relief of pain apparently by means of induction of nerve action; facilitating the restoration of resiliency to long immobilized tissue (as in fracture cases); increasing the blood flow; increasing capillary permeability; increasing the migration of antibodies across capillary tissues; increasing the migration of white cells to capillary tissues in areas of infection; the removal of the by-products of inflammation; change in the viscoelastic property of tissues; and, broadly, inducing a euphoric sense in the patient. The evidence was that the consensus of the medical profession was that the sole therapeutic effect of diathermy devices was in their heat producing capacity, and

BLEED THROUGH

POOR COPY

that the electromagnetic penetration considered independently as electromagnetic penetration was wholly without therapeutic value. The evidence was that the heat producing capability of radio frequency diathermy was a function of the average wattage delivered by the device to the human tissue. It was also the evidence that there was no way of determining externally and objectively the appropriate dosage for different physiological conditions and treatments, and that the therapist had to be guided by the heat response of the patient. The evidence was that patients have different tolerances for heat.

(Dr. Silverman apparently supposed that all diathermy devices were pulsing devices and in this respect, as the Court sought to point out to him, was quite wrong; a reference to Exhibit 69, which he drew, shows that he was confusing the input current from the household socket, which operates at the very low frequency of 60 cycles per second, and was thinking of alternating current as a pulsating rather than a continuous current. It is not. It is continuous alternating current. He thought, too, that half-wave rectification of 60 cycle domestic current was "pulsed" current. It is not so considered but is very familiar as rectified current. Neither 60 cycle unrectified current nor the 60 cycle rectified current is pulsed high frequency as used in describing the pulsed Diapulse machine, and the one or two other pulsed diathermic devices said to function at true diathermic heat therapy wattages. See Transcript June 14, 1972, pages 516-518).

BLEED THROUGH

POOR COPY

The elevation of the temperature of human tissue at depth through short-wave electromagnetic means takes place over time as the energy is applied and reaches a temperature plateau marking the balance between the evolution of heat in the tissue and the dissipation of the induced heat through the circulation of body fluids through the heat-elevated tissues, the heat itself stimulating an increase in such circulation; a cessation of application of the heat producing energy could significantly cool the tissue only over minutes of time. Hence, with such a device as the Diapulse, even operating at only 30 pulsations a second, the current flows for one 65 millionths of a second during each of 80 pulses a second. Each pulse measured from the moment the one 65 millionths of a second impulse starts to the moment when the next 65 millionths of a second long pulse starts at 30 pulsations per second would be what is called 12.5 milliseconds, that is, 12-1/2 thousandths of a second. No significant cooling after a significant elevation in tissue temperature could occur within 12-1/2 thousandths of a second. If the pulsations per second increase to 600 or to 2300 pulsations per second, the ratio of time "on" to time "off" rising, and the length of each individual "off" time varying inversely with pulse frequency, the cooling time would be ever more sharply curtailed as frequency rose, and the possibility of significant cooling would be ever more radically excluded. From this it follows that from the viewpoint of the heat treatment

BLEED THROUGH

POOR COPY

of tissue at depth, the "pulsation" of short-wave high frequency electromagnetic energy is significant only as a control on the average watts of energy delivered to the tissue over the whole period of treatment. The pulsation qua pulsation is therapeutically meaningless and does not function as a means of tissue cooling between intervals of tissue heating.

There is evidence that the use of a conventional diathermy device and the Diapulse device where each was producing the same average wattage produced no difference in effect on the subjects treated and that in consequence it was correct to conclude that the radically higher peak power interruptedly used in the Diapulse device produced no difference in its effect on the tissues from the effects produced at the same average wattage by conventional diathermy devices. There was evidence that further work along the same line showed no difference in the thermal or in the physiological effects of the conventional diathermy device and the Diapulse device on tissue when both operated at the same average wattage.

The evidence of Dr. Silverman was that the optimum amount of energy for therapeutic diathermy would be between about 50 and 100 watts and he was of the view that some diathermy equipment of the conventional sort was capable of delivering 200 watts of average power. Dr. Silverman's range of 50-100 watts referred, he explained, to the amount of electromagnetic emanation from the treatment head, and on the same test the Diapulse delivered 15 watts at the treatment head

BLEED THROUGH

POOR COPY

... he and his technical assistant "beefed up" the standard ...pulse device that they used. Dr. Silverman was satisfied ... no physiological effect produced by the Diapulse device ... traceable to anything other than its heat producing ef-..., even though the heat produced was, at most, mild heat, ... was equally produced by ordinary diathermy device used ... produce the same heat effect. The only identifiably electromagnetic effect produced by the Diapulse machine was one produced also by conventional diathermic devices, and that was the so-called pearl chain effect.

The evidence then fairly conducts to the conclusion that the Diapulse device produced at the treatment head, that is, at the point of application to the patient, only a very minor fraction of the wattage produced by conventional diathermic machines and that the diathermic, that is, the therapeutic heat capability of the Diapulse device was substantially nil. It was capable of modest elevation of tissue temperature because of the unavoidable effect of inducing electric current in human tissue, but such physiological phenomena as could be verified as flowing from the use of the Diapulse device were a consequence of its heat elevating effect, inadequate as that heat elevation effect was for general therapeutic purposes. The pulsed peak power characteristics of the Diapulse were meaningless from a therapeutic and medical modality point of view. To the extent that the Diapulse inevitably raised tissue

BLEED THROUGH

POOR COPY

temperature the "off" periods between the pulses of energy were insufficient in duration for any significant cooling effect to take place. Hence, neither the high peak power nor the pulsed nature of the Diapulse kind of electromagnetic energy had any therapeutic or medical significance. The electronic or electromagnetic capabilities of the Diapulse as a medical modality were bounded by and limited to the instrument's capacity to deliver an average wattage at the treatment head, at the point of its application to the human body. Neither pulsation nor peak wattage had any therapeutic utility or capability not evinced by conventional diathermic machines capable of producing the same average wattage at the point of application to the human body.

Exhibit W, descriptive of one form of P/EmF, with a rewritten brochure, has not precisely the same characteristics as Diapulses modified by the P/EmF conversion kit. Among other things it includes directions for the replacement of a 15,000 Ohm 2 watt resistor, R61, with a 33,000 Ohm 2 watt resistor to be connected from the potentiometer or variable resistor marked R60 to the chassis, with consequent increase of average wattage capacity from something in the order of 137 average watts to something in the order of 165 average watts. In addition, the lower range of pulse frequencies, 80-600, has been modified so that the lowest setting would deliver 3.6 average watts and the highest setting in the lower range would deliver 56 watts rather than the 35-38 watts characteristic of

BLEED THROUGH

POOR COPY

the Diapulse machine which was also, and evidently, the design capacity of the lower range of the P/EmF kits sent out in June, July and August of 1972. The device of Exhibit W, tested, however inadequately, for its capacity to raise the temperature of human deep muscle, had the capability when set at its very highest settings (6 and 12) in six of eight cases of elevating the deep muscle temperature to points between 40°C and 41.1°C; it thus could at its topmost pitch of effort just reach the minimum deep tissue heating requirement for classification as an acceptable diathermic apparatus under the American Medical Association standard (Exhibit Y). The test data in Exhibit W, Tab.VII, report that the initial temperatures of the deep muscle at the start of each test, except one, was above the core body temperature of 37°C which is normal for humans; the room temperature was 80°. There is no suggestion that the apparatus could function in the deep tissue range of 104° to 113°F. generally accepted as being the therapeutic range of standard diathermic treatment. Of the diathermic devices listed in the AMA manual, those which give their output in watts (and most of them do not) show outputs of 170-225 watts, 350 watts, 445 watts (with air-spaced plates) and 395 watts with hinged drum; all of these data are from the very early 1950's.

It was concluded when the government rested its case that it would be legal error to submit the case to the jury,

since the jury could not, on the evidence, find beyond a reasonable doubt that the shipment of the P/EmF to Las Vegas in June violated the temporary restraining order since its prohibition applied only, it fairly appeared, to Diapulse devices substantially identical with the one under seizure in Connecticut. Similarly, the charges of Paragraphs 6, 7, 8, 9 and 10, dealing with the shipment of P/EmF modification kits, it was concluded, could not without error be given to the jury to decide since on the evidence it was not considered that the jury could find beyond a reasonable doubt that the P/EmF kits were "articles of device known as DIAPULSE, or any similar articles of device . . . in whole or in part, assembled or unassembled," within the required plain meaning of the permanent injunction. The charge of Paragraph 11 was not supported by evidence from which it would have been possible for the jury to find beyond a reasonable doubt that the mailing involved was an act done with respect to an article held for sale which resulted in its being misbranded.

While the shipments of the kits were not of themselves shown to constitute criminal contempts that could be given to the jury on all of the evidence it must be concluded that shipments of the P/EmF kits, and the use of equipment connected through use of the kits, constituted evasion and not in spirit of the strictures of the permanent injunction and its purpose. The same conclusion must be reached as to kits made up in conformity to Exhibit W. Both the kits shipped in

BLEED THROUGH

June, July and August of 1972 and any kits made up in accordance with Exhibit W, would in no sense be conventional diathermic modalities of the kind used and useful in diathermic heat therapy. On the contrary, kits of either type would enable practitioners already learned in the use of Diapulse to continue the use of the devices as Diapulse modalities in accordance with the teachings of defendant over the years. The addition of an extended range making possible the use of pulse frequencies as high as 2800 pulsations per second and 137 watts of average power (with peak power at 753 watts at that point) does not alter the case. It may be that by using the device to deliver its greatest average wattage at the settings of 12 and 6, the device could, in a room where the temperature is 80°, barely reach in six-eighths of the instances of its application the lower edge of the range of tissue temperatures at depth at which diathermic heat therapy is administered, but that hardly constitutes the articles standard diathermic heat-therapeutic devices. They would remain characteristically devices essentially designed and suited to implement Diapulse therapy, that is, the use of electromagnetic induction with minimal increase in tissue temperature as electromagnetic therapy accompanied by some unavoidable but unsought-for increase in tissue temperature.

The present set of proceedings was commenced at the end of 1969. In the 3 years that have elapsed since that seizure, it is apparent from the testimony in the present case

BLEED THROUGH

that the defendants have not retreated from their obdurate insistence on pursuing their own scheme of therapy, and that defendant and its responsible officers have not at any time sought genuinely to depart from adherence to their conviction but, rather, have sought repeatedly to induce the Food and Drug Administration to authorize activities which paid lip-service to heat therapy through the use of electromagnetic energy while in reality making it possible to put back into service the thousands of Diapulse devices already in existence and to ship more such devices with such minimal additions to the by-product heat producing capability of the Diapulse device as would enable it to pass muster in mild temperature diathermic heat therapy while remaining essentially an electromagnetic device which, it could always be argued, produced its physiological effects, if any, through electromagnetic therapy and not through heat therapy. The modality would have remained at all times a pulsed device characterized by having its current "on" a minor part of the time (in Exhibit W, 13.2% of the time at the highest pulse frequency and one-half of 1% of the time at the lowest pulse frequency). The device would have very high peak power (ranging up to 2153 watts at the lowest pulse and highest "penetration" settings). The practitioner would possess this modified instrument and his one-sided indoctrination over years of practice with Diapulse in electromagnetic therapy, based on knowledge of the extensive literature sent him by defendants; the instrument in his possession would have as its major and ineffaceable design

BLEED THROUGH

characteristic capabilities that had no explanation except their selective suitability to the practice of electromagnetic therapy as such and as contrasted with diathermic heat therapy.

At the same time it must be recognized that the economic waste that will inevitably be implicit in the systematic surrender for destruction of all existing Diapulse devices (except those that can be used under proper controls for experimental purposes by responsible investigators) is desirably avoided if that is possible without compromise of the principle of the Connecticut decision and of the decision in this Court of Judge Rosling. In addition, the defendants are entitled to a clear command and the government to a rigorous order so that there cannot be any evasion and extirpation is effective.

It would appear that Paragraph II of the permanent injunction should be elaborated and refined so that Section III of the decree will have its intended effect. The proposal of the government to add a new set of paragraphs, rather than to modify the existing paragraphs would present a decree of great length and since it would be desirable to have the entire decree in a single document for rapidity and ease of dissemination and understanding, it would be desirable to avoid repetition. Section VIII as suggested by The Government's suggested Section VIII par. B and par. C appear superficially to be identical with Section III par. A sub pars. 1 and 2 of the present permanent injunction, and that can be avoided.

BLEED THROUGH

Proposed Section VIII par. A introduces the critically new matter. Suggested par. A, while apt to describe P/EmF, may well have the disadvantage of specificity in the present context.

Section II might be rephrased thus:

"The DIAPULSE devices referred to in this injunction include in addition to the DIAPULSE devices heretofore sold in this country and abroad as Models D-100, D-100J, D-101, D-102, and D-103; the said devices or any of them as modified to convert them into P/EmF devices (as described in Exhibits etc.), and the components or kits or parts of any assemblies or sub-assemblies thereof used to effect such conversions; any short-wave, high frequency, electromagnetic modality made or adaptable to radiate pulsed short-wave high-frequency, electromagnetic energy unless (a) the peak power available at any setting of the device does not exceed twice the average wattage at such setting, and (b) it is capable of raising the temperature of deep human tissue at a depth of 2 inches in the thigh muscle of living human subjects from a core body temperature of 98.6° to 104°F in 20 minutes or less, at a majority of its operational settings, and (c) it is capable of raising such tissue at such depth to a range of temperatures from 104° to 113°F at a series of readily selected settings of the device."

The language of Section III, par. A should be modified, probably in the part preceding sub pars. 1, 2 and 3 to

over conversion assemblies, subassemblies, kits, components, or instructions, manuals or pamphlets. In Section IV, the reference to 21 C.F.R. 1.106 ought probably to be clarified and expanded to make clear that it covers any device included Section II, and consideration should be given to the matter of requiring defendants to clear any medical modality that they desire to sponsor or disseminate in this country. It should be understood that the advance clearance requirement is not normally required for devices but is exceptionally required in this case and consciously borrows from new drug procedures.

A new section or sections, functioning as did Section V, should be in the amended decree and, perhaps, Section V can be retired as fully performed and devoid of prospective effect. Proposed modifying paragraphs should be settled on notice and either party is free to propose appropriate language within the limits indicated by the sense of this decision. Ten days notice of settlement is to be given to the other side so that there will be ample time to exchange ideas before the amendatory language is adopted. The adoption of the amendatory language which can appropriately take the form of an amendatory decree should be followed by a resettlement of the entire decree so as physically to incorporate the new material.

Paragraphs IX and X, as proposed by the Government, present points of principle as to which the defendants should properly be heard on the settlement of the further decree.

It is so ORDERED.

Dated: Brooklyn, New York
May 7, 1974.

U. S. D. J.

FOOTNOTES

1. Exhibit 67 seems to be the set of instructions sent to Groves in Missouri from New Hyde Park.

2. See 21 C.F.R. § 1.3 for the propriety of the Court's language.

Table A - Diapulse
D101 - D102

Pulse frequency per second	Dial at	Peak and Average Power in Watts 1	2	3	4	5	6	* "Duty Cycle"
30	1	293	390	488	585	780	975	1/2 of 1
		1.52	2.03	2.53	3.04	4.05	5.07	
100	2	293	390	488	585	780	975	1.
		3.04	4.05	5.07	6.08	8.1	10.1	
300	3	293	390	488	585	780	975	1.9
		5.7	7.6	9.5	11.4	15.2	19	
400	4	293	390	488	585	780	975	2.6
		7.6	10.14	12.68	15.2	20.3	25.3	
500	5	293	390	488	585	780	975	3.25
		9.5	12.65	15.85	19	25.3	31.6	
600	6	293	390	488	585	780	975	3.9
		11.4	15.2	19	22.8	30.4	38	

*That is, the percentage of each second during which the "current" is "flowing" at the pulse frequency shown at the left.

Each "pulse" is 65 millionths of a second in duration.

Peak power is given in upper line, average power in lower line at each pulse frequency setting.

The device operates at 27.12 megaherz frequency.

The power source required is 117 volt 60 cycle AC current at 5.5 amperes.

BLEED THROUGH

Table B - 2/2 of 2
RS 2800
(Exhibit W)

Pulse Frequency (pps)	Dial at	Peak and Average Power in Watts 1	2	3	4	5	6	*"Duty Cycle"
80	1	1653 8.6	1730 9	1776 9.03	1788 9.3	1846 9.6	2153 11.0	1/2 of 1%
140	2	1451 15.1	1480 15.4	1548 16.1	1586 16.5	1615 16.8	1817 18.0	1.04%
200	3	1358 26.5	1379 26.9	1384 27.0	1400 27.3	1400 27.3	1512 30.9	1.95%
300	4	1357 35.3	1349 35.8	1392 36.2	1415 36.8	1423 37.0	1588 41.3	2.6%
400	5	1276 41.5	1307 42.5	1326 43.1	1341 43.6	1378 44.8	1516 49.3	3.25%
600	6	1261 49.2	1264 49.3	1282 50.0	1333 52.0	1358 53.0	1487 56.0	3.9%
680-700±	7	1325 51.7	1341 52.3	1356 52.9	1420 55.4	1420 55.4	1461 56.0	3.9% ± 10%
1000	8	1186 77.1	1209 78.6	1232 80.1	1255 81.6	1278 83.1	1307 85.0	6.5%
1500	9	985 102.5	1000 104.1	1018 105.9	1034 107.6	1050 109.3	1051 109.3	10.4%
2100	10	827 112.9	852 116.4	866 118.3	879 120.1	893± 121.9	893 123.8	13.65%
2500	11	728 118.3	750 121.9	761 123.8	772 125.6	796 129.4	800 131.0	16.25%
2800	12	659 120.1	669 121.9	700 127.5	710 131.0	732 135.0	753 137.2	18.20%

*That is, the percentage of each second during which the "current" is "flowing" at the pulse frequency shown at the left.

Each "pulse" is 65 millionths of a second in duration.

Peak power is given in upper line, average power in lower line at each pulse frequency setting.

The device operates at 27.12 megaherz frequency.

The power source required is 117 volt 60 cycle AC current at 5.5 amperes.

BLEED THROUGH

Judge Rosling Decision, June 9, 1972 After Trial

FILED
CLERK'S OFFICE
U.S. DISTRICT COURT E.D. N.Y.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK JUN 9 1972 ★
- - - - - - - - - - - - - - - - - -x
UNITED STATES OF AMERICA,

Plaintiff,

-against- 68-C-391

DIAPULSE CORPORATION OF AMERICA
also known as THE DIAPULSE
MANUFACTURING CORPORATION OF
AMERICA, a corporation,

JUN 9 1972

Defendant.
- - - - - - - - - - - - - - - - - -x

Appearances:

ROBERT A. MORSE, ESQ.
United States Attorney
Eastern District of New York
Attorney for Plaintiff

Cyril Hyman, Esq.
Assistant U. S. Attorney
Of Counsel

BASS & ULLMAN, ESQS.
Attorneys for Defendant

Milton Bass, Esq.
Of Counsel

ROSLING, J.

Pleadings

Complaint

The action was commenced in this court on April 25, 1968, by the filing of the complaint. It alleges the following:

BLEED THROUGH

POOR COPY

The action is brought under section 302(a) of the Federal Food, Drug, and Cosmetic Act, ["Act"], 21 U.S.C. § 332(a), which empowers the district courts to restrain violations of section 301(a) and (k) of the Act, 21 U.S.C. § 331(a) and (k). The sole defendant, Diapulse Corporation of America, etc., ["Diapulse" corporation or company] is incorporated in Delaware doing business and having its principal place of business at New Hyde Park, [Nassau County], New York.

Diapulse's business is the promotion, selling, and introducing and delivering for introduction into interstate commerce a device[1/] intended for use in the cure, mitigation, treatment and prevention of disease in man. Although resemblin a medical diathermy unit[2/] it purports to achieve its therapeutic results without generating heat.

In the interstate sale and distribution of the device the Diapulse company utilizes written, printed and graphic matter which comprises the labeling of the device, organizes symposia, sponsors meetings and has exhibits and salesmen at meetings of osteopaths, chiropractors and physicians at which false and misleading representations are made orally and in labeling as to the mechanism of action and effectiveness of the device in the treatment of disease and in affecting the functions and structure of the human body, and the Diapulse company has neither corrected nor repudiated any of such claims

BLEED THROUGH

POOR COPY

or misrepresentations.

The labeling falsely and misleadingly represents the mechanism of action of the device by claiming the following:

(a) It treats the human body by pulsed electromagnetic energy without heat.

(b) It stimulates the reticuloendothelial system ["RES"], thereby stimulating the body's defense and repair mechanisms to speed tissue and healing response.

(c) It allows heat to dissipate between pulses and therefore has no build up of heat.

(d) It operates at the cellular level by non-thermal effects.

The labeling further falsely and misleadingly represents the effectiveness of the device both when used alone and as an adjunct to chiropractic, osteopathic, and medical measures in treatment for the following:

A. Stimulating the RES (the body's defense mechanism) and tissue response and changing blood composition as set forth in Appendix A, annexed to the complaint. The Appendix enumerates 59 effects upon the body which the use of the device is represented to have or, in a few instances, to benefit.

BLEED THROUGH

POOR COPY

B. Infections and systemic infections and diseases including but not limited to 75 conditions and diseases specified in Appendix B.

C. Inflammatory and chronic conditions of which 93 are listed in Appendix C, and other related conditions.

D. Circulatory and metabolic disorders, 53 such diseases or effects in man and 9 in horses being listed.

E. A variety of symptoms which are allegedly benefited by the use of the device of which 23 are enumerated in Appendix E.

The complaint then cites for its res adjudicata effect an in rem proceeding entitled United States v. One Article of Device * * * Diapulse in which the Court of Appeals of this circuit, 389 F.2d 612 on January 30, 1968, affirmed a judgment of the District Court of Connecticut entered in 1967.[3/]

Notwithstanding such adjudication defendant, it is further alleged, has not corrected or repudiated any of such claims or representations, but continues to make and use them.

The complaint then charges that defendant is violating Act section 301(a), 21 U.S.C. § 331(a), by causing the introduction and delivery for introduction into interstate

BLEED THROUGH

POOR COPY

commerce of the device which is misbranded within the meaning of Act section 502(a), 21 U.S.C. § 352(a); further, that the defendant violates Act section 301(k), 21 U.S.C. § 331(k), by causing said device to be so misbranded while it is held for sale after shipment in interstate commerce.

The single cause of action pleaded concludes with allegations that unless defendant is restrained generally it will not discontinue its holding for sale and distribution of the device in interstate commerce and its violation of 21 U.S.C. § 331(a) and (k).

The "Wherefore" claims are longer than the body of the complaint proper.[4/] The capitulations of the relief sought are set forth in the following:

1. A general injunction under 21 U.S.C. § 332(a) against causing the device or any similar device to be introduced or delivered for introduction into interstate commerce in violation of § 331(a) by reason of its being misbranded within the meaning of § 352(a) or (f)(1); and against doing any act which causes the device, etc., to become misbranded while held for sale after shipment in interstate commerce, in violation of § 331(k).

2. An injunction as in subd. (1), supra, against introduction etc., of the device with any claims whatever as

BLEED THROUGH

POOR COPY

to the device's effectiveness or mode of action in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animal, unless and until defendant should prepare, assemble and submit scientific evidence of its claims and revised labeling to the Food and Drug Administration in conformity with 21 C.F.R. 1.106 and should obtain approval of the matter submitted.

3. A requirement that defendant give notice of the Connecticut court's adjudication to every person known to defendant to have purchased or leased or to be in possession of a Diapulse device, and to its distributors and sales representatives and others.

4. Similar injunctive relief during the pendency of the action.

5. A temporary restraining order.

Answer

The defendant's answer consists of a general denial and three affirmative defenses.

The first defense alleges that the decree of condemnation of the device authorized defendant to relabel it under the supervision of the District Court of Connecticut. Defendant accordingly purports to find that "the instant

BLEED THROUGH

POOR COPY

complaint is in conflict and inconsistent with the said decree in that it seeks to vary, modify and overrule the Connecticut decree and to interfere with the rights thereunder conferred upon the defendant herein."

The defense alleges further that the Diapulse company's good faith efforts to negotiate with the Food and Drug Administration to comply with the decree of condemnation and relabeling provisions have been arbitrarily rebuffed and should be held in abeyance pending final determination of all appeals from the Connecticut decree of condemnation.5/

The second defense was that the Government had

> failed to obtain an adjudication in its favor with respect to 72 [sic] specifically enumerated issues raised by the pleadings and tried in the United States District Court for the District of Connecticut, and now seeks, by the instant action, to relitigate said issues. As such, plaintiff should be barred and estopped from harassing, annoying, and interferring with the lawful pursuit of the defendant's business."

The third defense declared that this court was

> "without jurisdiction to grant the relief requested by plaintiff in the third paragraph of plaintiff's prayer for relief * * * [a permanent injunction pending receipt from defendant by Food and Drug Administration of evidence and approval by Food and Drug Administration of device as relabeled] * * * because said request for relief is contrary to the decree of condemnation and relabeling in the Connecticut action, and no statutory authority exists for same."6/

BLEED THROUGH

POOR COPY

The Connecticut Suit

The Libel

On December 16, 1965, the Government filed a libel of information in the United States District Court for the Northern District of Georgia, Atlanta Division, against a Diapulse device and certain literature. The in rem proceeding prayed for seizure and condemnation of the device pursuant to 21 U.S.C. § 301 et seq.

The libel charged that there was at Atlanta, Georgia, in the possession of James E. Tebbel, D.C., doing business as Buckhead Chiropractic Clinic, such device labeled in part by a metal plate affixed to it and inscribed as follows:

> "Diapulse Serial No. 1824
> Model D * * * Diapulse Manufacturing
> Corporation of America New York City
> Manufactured by Remington Rand
> Division Sperry Rand Corporation * * *"

The device had been shipped prior to December 9, 1963, by the Diapulse corporation to one Drakes in Atlanta, a former representative of the company who delivered it to Tebbel. Additionally, Tebbel had in his possession items of promotional material which had been either mailed to him by Diapulse or received from Drakes in person who had in turn received them from Diapulse.

BLEED THROUGH

POOR COPY

Judge Rosling Decision, June 9, 1972

Misbranding of the device under 21 U.S.C. § 352(a) existed in that its labeling, namely the promotional material accompanying the article, represented and suggested that the article was adequate and effective for treatment of [here follows a lengthy list of diseases and claims of stimulating, enhancing, restoring, reenergizing, increasing, revitalizing, various systems, functions, mechanisms, etc. of the human body] whereas said statements were false and misleading since the article was not adequate and effective for the purposes claimed in the statements.

The article was, accordingly, liable to seizure and condemnation pursuant to 21 U.S.C. § 334 for which relief a prayer was presented.

The answer filed three months later on March 16, 1966, by the Diapulse Corporation of America as claimant pleaded a general denial and asked for a dismissal of the libel.

The action was thereafter at the instance of the Diapulse company transferred to the District Court of Connecticut. 7/

Trial was begun before Judge Blumenfeld and a jury on February 21, 1967, and continued through March 17, 1967, when the jury returned its verdict for the government libellant. The verdict was in writing and was comprised of two parts: a

BLEED THROUGH

general verdict, and what was entitled by the court as a "Special Verdict Form," but which in fact consisted of answers to about 40% of the interrogatories propounded to the jury by the court. (See Fed. R. Civ. P. 49(b) for procedure). Judge Blumenfeld had submitted to the jury 117 diseases, disorders and bodily conditions claimed to have been misrepresented, with instructions by the court that only if the jury found a general verdict against Diapulse of misbranding was it to "turn to" the interrogatories.

> "On the three accompanying pages," Judge Blumenfeld had charged, "there have been listed those diseases, disorders and conditions for which the government has alleged that false or misleading claims were made by the labelling. In the event your verdict is for the government, write the word 'Yes" in the blank space before each of those diseases, disorders and conditions for which you find false or misleading claims were made.
>
> "Have each sheet signed by your foreman."

The charge then continued:

> "'If you should find that one or more of the claims has been proved false or misleading, I will ask that you indicate what those claims are. * * *
>
> * * *
>
> "'In the event your verdict is for the Government, if you reach the point where your verdict is for the Government write the word "yes" in the blank space before each of those [items] for which you find, if you so find, that false or misleading claims were made and have each sheet signed by your foreman. * * *

BLEED THROUGH

POOR COPY

Judge Rosling Decision, June 9, 1972

10..

> "'I am not going to ask you to go through the vast list of 120 [sic] and deliberate upon each one, but go to those -- if you reach them at all, which, in your view, represent the heart of the claims that were made. * * *
>
> * * *
>
> "'And still there are too many of them here, 120, to try and manage or even justifiably ask you to pass on each and every one of them. So that is why I say go through the list, but pick out those which you think go to the heart of the claims that are made here and pass only upon those. * * *'"

The jury with surprising diligence answered no less than 49 of the 117 interrogatories by the word "Yes," meaning under the instructions of the court that false or misleading claims had been made as to them. The remaining interrogatories were left unanswered.

Later, when an appeal was taken to the Court of Appeals from the judgment of condemnation entered on the verdict as amended [8/] that court in its opinion on affirmance gave short shrift to Diapulse's claim "that the judgment is defective in making a general finding in favor of the government when, so it is alleged, the jury issued a special verdict in which it found for the appellant on 72 [sic] of 121 [sic] issues."

The opinion continues:

11.

> "Although the form submitted to the jury on which the 121 [sic] issues were listed is headed 'Special Verdict Form,' there was no special verdict in this case. Judge Blumenfeld clearly instructed the jury that if they found one or more false claims of effectiveness, in the labeling, their verdict should be for the government. He then requested that if their verdict should be for the government, they should write 'Yes' in the blank space before each disease, condition, etc. listed on the form as to which they found that false or misleading claims had been made. At another point in the charge, he instructed the jury only to pick out those which they thought went to the heart of the government's claims. His reason in doing this was, as he explained, to help prevent the possibility of compromise among the jurors, and to require instead that they reach agreement on at least one claim before finding for the government. The jury returned a general verdict: 'In this case the jury finds the issues in favor of the libelant and therefore finds that the device is misbranded.' Clearly, the action taken by the court in also requesting the jury to specify some of the claims which it found false or misleading was the submission of special interrogatories, and not a request for a special verdict. Compare Rule 49(a) with Rule 49(b), Federal Rules of Civil Procedure."

The appeal was argued before the Court of Appeals on January 9, 1968, and decided three weeks later on January 30. Before the matter reached the appellate court, however, a number of proceedings following the jury verdict of March 17, 1967, had supervened.

Judgment, signed by the clerk of the Connecticut court was made and entered March 31, 1967. It adjudged in

12.

three brief decretal paragraphs that the single article seized was misbranded within the meaning of the Act § 502(a), 21 U.S.C. § 352(a) (1964),[9] and pursuant to Act § 304(a), 21 U.S.C. § 334(a)(Supp. 1967)[10] as amended it was condemned and forfeited to the United States; further, that pursuant to Act § 304(e), 21 U.S.C. § 334(e)(1964), the government should recover costs, fees, storage and such other proper expenses to be taxed; and, finally, that on or before May 8,1967, the "owner or proper claimant of said device shall show cause why said device shall not be destroyed."

In response to said final decretal provision the Diapulse corporation moved for an order amending the judgment in order to provide for an opportunity to relabel the seized article. Diapulse's petition, brought under Act § 304(d) as amended, 21 U.S.C. § 334(d) (Supp. 1967), prayed that the device should be delivered to it so that it might proceed with the relabeling in conformity with the statute, and the court amended the judgment accordingly.[11] The court's amendments of the judgment are too numerous and detailed for complete summarization at this point. Suffice it to say, however, that the amended judgment directed that the device was to be surrendered to the Diapulse corporation under bond so that it might bring it into compliance and Diapulse was forbidden to

BLEED THROUGH

POOR COPY

> "ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare * * * shall in writing have released such article for shipment, sale, or other disposition." If Diapulse "does not avail itself of the opportunity to repossess the condemned article in the manner aforesaid, the United States Marshal for this [Connecticut] district shall retain custody of said article pending the issuance of an Order by this [Connecticut district] court regarding its disposition; * * *."

Judge Blumenfeld additionally directed that he was to retain jurisdiction "to issue such further Decrees and Orders as may be necessary to the proper disposition of this proceeding" and, finally, that the force of the amendatory orders be stayed pending disposition of an appeal if taken.

Diapulse had moved for judgment notwithstanding the verdict, and in the alternative for a new trial.[12/] Judge Blumenfeld considered both motions and on May 24, 1967, denied them in an opinion which is reported at 269 F. Supp. 162. The content of the opinion will be considered, as pertinent and required, in the later discussion of the opinion of the Court of Appeals upon affirmance to which we immediately turn. Eight months were to elapse, however, following Judge Blumenfeld's denial of the Diapulse's motions for judgment etc., before the Court of Appeals rendered its decision of affirmance on January 30, 1968. The Court of Appeals found that Diapulse appealed upon five claims on each of which it sustained the holding of Judge Blumenfeld.

14.

The first claim urged by Diapulse was that since there was an honest difference of opinion among medical experts with respect to the issues of effectiveness raised in the libel, there could be no proof that the statements were false in fact and the issues should, therefore, never have been submitted to the jury. The Court of Appeals upheld Judge Blumenfeld's conclusion in ruling on the defendant's motion for judgment n.o.v., that "the evidence demonstrated the existence of scientific standards capable of testing the degrees of effectiveness of a product." Hence, it was proper to submit the issues to the jury.

The second claim based on Judge Blumenfeld's submission of the case to the jury for a general verdict accompanied by answers to interrogatories has already been discussed, (pp. 10 and 10a, supra). Rejecting appellant's contention that a general verdict should not have been rendered, but that the jury should have been required to rule on every one of the 121 [sic] interrogatories, the Court of Appeals noted that the statute in relevant part provides (21 U.S.C. § 352) that "A drug or device shall be deemed to be misbranded -- (a) If its labeling is false or misleading in any particular." (Underscored phrase italicized for emphasis in opinion by Court of Appeals.)

The opinion of the Court of Appeals continues:

> "It is argued that because there was a general judgment, and it is not clear what the jury specifically found, appellant will not be able to properly relabel its product. As Judge Blumenfeld said: 'Claimant mistakes the purpose of a court. It is not a pharmaceutical testing house.' Admittedly it would be easier for the claimant in an action such as this to go forward with relabeling its product if the judgment were more specific, but the purpose of the action is simply to condemn the drug, machine, etc. if misbranded (see discussion above), and the action is provided for by statute. The initial determination of the legality of the new labeling is for the administrative body."[13/] [Emphasis supplied.]

The third claim of Diapulse which the Court of Appeals overruled was the argument that Judge Blumenfeld

> "changed the issues raised by the libel when it instructed the jury that it could find for the government if it found that there was a difference of opinion among medical experts which was not disclosed in the labeling."

Agreeing with Judge Blumenfeld's holding in this regard, the Court of Appeals declared (p. 615 id.):

> "But this was not a new issue. 21 U.S.C. § 321(n) reads:
>
> > If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested * * * but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect

BLEED THROUGH

POOR COPY

> to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

This has been read broadly, and not improperly, in 21 C.F.R. § 1.3:

> The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

Cf. Research Laboratories, Inc. v. United States, 167 F.2d 410, 422 (9 Cir. 1948)."

The fourth point Diapulse tendered, but failed to sustain was that

> "it was error for the District Court to rule, as a matter of law, that reprints of medical articles constitute 'labeling' within the meaning of the statute. It is argued that an article, journal or book does not become labeling for any drug or medical device which a doctor (or chiropractor) may have in his office. That is no doubt true. See United States v. 24 Bottles 'Sterling, Vinegar, & Honey, etc.' (Balanced Foods, Inc.), 338 F.2d 157 (2 Cir. 1964), cited by appellant. But the essential question is whether the printed material seized with the device supplements or explains the device -- it is the textual relationship, not physical attachment, which is significant. See Kordel v. United States, 335 U.S. 345, 69 S. Ct. 106, 93 L. Ed. 52 (1948); and United States v. Urbuteit, 335 U.S. 355, 69 S. Ct. 112, 93 L. Ed. 61 (1948). Here, the claimant admitted distributing all of the

BLEED THROUGH

POOR COPY

> material seized with the device. A reprint of a 'medical article' need not be treated differently from other printed material alleged to constitute labeling. See United States v. Hoxsey Cancer Clinic, 198 F.2d 273 (5 Cir. 1952), cert. denied 344 U.S. 928, 73 S. Ct. 496, 97 L. Ed. 714 (1953)."[14/]

The fifth and last of the points unsuccessfully urged upon Judge Blumenfeld and the Court of Appeals by Diapulse was "that it was error to allow the introduction of evidence, including opinion testimony, about a medical device called 'Theramatic,' because that device and appellant's device are not the same."

The Court of Appeals ruled that "[o]n the evidence adduced, it was not error to hold that the machines were sufficiently similar to allow introduction of evidence as to 'Theramatic,' for purposes of evaluating 'Diapulse'."[15/]

Certiorari was, as earlier noted, denied by the Supreme Court on June 10, 1968, 392 U.S. 907.

In the meantime, at long last, the lethargic government had bestirred itself and had on April 25, 1968, filed its complaint. It is perfectly plain that had the government filed its suit one year earlier, in 1967, and immediately applied for an injunction comparable in scope to that which prevented the Diapulse corporation from disposing of the single machine forfeited in the Connecticut in rem suit until the device had

been brought into compliance with what the Food and Drug Administration required and it had been released by the Food and Drug Administration, the Diapulse corporation would have been put out of business pending such compliance, provided the rest of the machines it marketed were substantially identical with the forfeited device and the labeling by accompanying literature was substantially the same as was found in the Georgia chiropractor's office.

In the trial ultimately conducted before this court it was practically conceded that the business of Diapulse consisted of the disposition by sale of only two models of the device which except for some minor details not pertinent to the instant issues were substantially identical with the condemned device. Further, the proof was overwhelming that until some time in 1968 no attempt whatsoever had been made to modify the promotional claims Diapulse had been making or implying in marketing its product.

But the slow pace at which the Food and Drug Administration moved against Diapulse gave that company the opportunity to continue its obfuscating tactics and the recklessness to engage in them. 16/

On April 29, 1968, Judge (now Chief Judge) Mishler signed an order to show cause for a preliminary injunction upon the government's application, returnable May 6, 1968. 17/

The show cause order did not, as the temporary restraining order had, track the precise findings of the jury in what was sought to be enjoined.

Instead, the Golden supporting affidavit in Exhibit III annexed thereto purported to establish categories of certain of the affirmative jury findings of misrepresentation and under these headings to list post-verdict representations which Diapulse made concerning the efficacy of its device. Most of these subsequent representations would on simple inspection by non-medical laymen be seen to be a brazen paraphrase of and even literal persistence in the adjudicated misbranding. In the case of other representations medical testimony would have to be supplied to subsume the language thus used after the trial under the adjudicated expressly forbidden categories.

Mr. Golden and the supporting affidavits of the Food and Drug Administration agents Everline and Eastwood earlier referred to, cited a number of specific sales of the device thus misbranded in the post-judgment period.[18/]

Both the temporary restraining order and the motion for a preliminary injunction speedily became moot, for on May 7, 1968, Judge Mishler on the consent of defendant issued a preliminary injunction. The order recited:

BLEED THROUGH

> "[C]ounsel for the respective parties having met and advised the Court that defendant agrees to the issuance of a Preliminary Injunction, as hereinafter set forth, for purposes of effectuating an orderly procedure pending trial and determination of this action and without admitting the allegations of fact or law set forth in the Complaint filed herein; and upon the Consent of the defendant, annexed hereto."

The order followed in his verbis the restraints imposed by the temporary restraining order, rather than those sought by the motion for a preliminary injunction, but extended them for the period pending trial and determination of the action. The government's motion for such injunction returnable May 6, 1968, was declared withdrawn.

The defendant had already laid its plans to evade the restraint even as the order was being signed. These were not long delayed in their disclosure. On May 6, 1968, four days after the injunction order was signed defendant addressed a letter to all its dealers and dealer salesmen, throughout the country informing them that

> "[a]fter lengthy litigation (which is still pending for consideration before the United States Supreme Court), a judgment was obtained by the Food and Drug Administration to the effect that 49 specifically enumerated claims, out of 121, may not be made for Diapulse units, directly or by implication."

The letter then announced with full bold-faced capitalization that

BLEED THROUGH

"72 CLAIMS, HOWEVER, WERE NOT RESOLVED IN FAVOR OF THE FOOD AND DRUG ADMINISTRATION."

The letter next explains with a certain magnanimous condescension that

"On May 1, 1968, without admitting any of the allegations of fact or law as set forth in the complaint, we voluntarily [sic] agreed that an order be entered temporarily prohibiting the shipment or sale of Diapulse units with any of the 49 representations or suggestions, as shown in the attached order."[19] (Emphasis supplied)

Following this, the letter, again reverting with true Madison Avenue salesmanship to full capitalization further emphasized by underscoring, declares:

"THE COURT DOES NOT AFFECT THE COMPANY'S RIGHT TO CONTINUE THE SHIPMENT, SALE AND SERVICING OF DIAPULSE UNITS, EXCEPT FOR THOSE CONDITIONS STATED IN THE 49 CLAIMS.

"DIAPULSE MAY CONTINUE TO BE RECOMMENDED AS ADJUNCTIVE THERAPY IN THE TREATMENT OF THE FOLLOWING CONDITIONS, EXACTLY AS STATED:"

The jury under explicit authority from the court had left 68 interrogatories concerning diseases, disorders and bodily conditions unanswered. Defendant's circular with arrogant effrontery, wholly contrary to the spirit and letter of Judge Blumenfeld's injunction, listed 25 of the 68 diseases as ones for which it was proper, therapeutically and legally, to continue to use its device.

Following the enumeration of these 25 the letter continues:

Judge Posting Decision, June 9, 1972

22.

"To avoid any misunderstanding, and to assure complete compliance with all applicable rulings of the Court with respect to the purposes and uses of Diapulse in the treatment of various diseases, conditions and symptoms, you are to return to us immediately all literature, brochures and treatment charts with the exception of the following, which you may continue to use:

'Experimental Acceleration of Wound Healing,' Bruce M. Cameron, M.D.

'Peripheral Blood Flow Measurements During Application of Pulsed High Frequency Currents,' William James Erdman II, M.D.

'Congressional Record' (261-385-7904)

"Further, no oral statements, representations, or suggestions shall be made which directly or indirectly, indicate, refer, represent, suggest, or create the impression that Diapulse is an adequate and effective treatment for any of the 49 purposes, conditions or diseases listed in the annexed order."20/ (Underscoring in original.)

The letter concludes with advice that the treatment chart and literature are being revised "in accordance with the foregoing" and a bland playing down of what had been adjudicated against it by a pious affirmation that "[a]s always, it has been, and still is the company's policy to comply with all applicable rules and regulations concerning the sale and use of Diapulse." (Emphasis supplied.)

The proof came as no surprise at the instant trial that defendant continued to sell its device after the jury's verdict without making any disclosure to the purchaser that its use-

fulness had been questioned in litigation until misrepresentation and misbranding had been adjudicated.

One further proceeding in the Connecticut suit remains to be mentioned before we turn to a consideration of the pre-trial procedures in the Eastern District action.

On June 10, 1969, exactly one year after the Supreme Court had denied certiorari, Diapulse as claimant filed a motion before Judge Blumenfeld to further amend the 1967 judgment of forfeiture.

The gravamen of the motion was as follows:

Diapulse in a long series of meetings with the Food and Drug Administration both before and after the Connecticut action, "attempted to amicably negotiate relabeling for its article of device, only to be rebuffed at every turn."

Claimant in extensive correspondence with the Food and Drug Administration, submitted to Judge Blumenfeld as exhibits, "has in good faith offered to bring its article of device in compliance with the law, only to receive continued rebuff and nonresponsive answers."

After several paragraphs of like tenor the motion continues:

"16. That Claimant has relabeled its device so that it is in complete compliance with the law, that is, it claims that its device is adequate and effective for use in treating the following medical conditions:

(a) Tissue and bone healing;

(b) Sinusitis;

(c) Bursitis;

(d) Arthritis;

(e) Blood flow to peripheral areas;
(See Exhibit GG)

"17. That the article of device is, in fact, adequate and effective for use in treating the foregoing medical conditions.

"18. That the claim that the article of device is adequate and effective for use in treating the foregoing medical conditions in no way contravenes the findings of the jury and the decision of this Court in the above-entitled action;

"19. That this Court has continuing jurisdiction over this matter and that the terms and conditions regarding the relabeling of the article of device are clearly to be fixed by the Court and not by the Food and Drug Administration, as is more fully noted in the attached 'Points and Authorities in support of Motion.'"

The motion concludes with a "Wherefore" clause praying for an order further amending the judgment by decreeing "that the device has been brought into compliance with the law when labeled as being an adequate and effective treatment for the afore-mentioned medical conditions * * *."

Judge Blumenfeld summarily disposed of the motion on June 24, 1969 by his two-word inscription in the margin on the first page, "Motion Denied." He wrote no opinion.

As for the seized device itself, it has according to proof adduced at trial never left the Clerk's office in Connecticut where it continues to gather dust. The Food and Drug Administration, presumably, has never found anything therapeutic which the machine is capable of as to which truthful representations may be made, nor does it appear that defendant is prepared to make them. Accordingly, it is not surprising that the Food and Drug Administration has not given the requisite consent to the further distribution of the device in interstate commerce.

Pretrial Procedures and Trial in the Eastern District of New York

On November 11, 1971, the Court filed an opinion which directed the issuance of a preliminary injunction against the defendant, and on December 8, 1971, a decision constituting its findings of fact and conclusions of law upon such preliminary injunction. Appended to these findings and conclusions was the formal order of the Court providing for such pendente lite injunctive relief.

With a view to enabling defendant to apply within a brief period for a stay pending appeal the Court in such order authorized defendant to continue its ordinary and usual operations and disposition of Diapulse devices in the ordinary course of business, with the proviso that the order was to be fully effective in its restraints on and after December 15, 1971.

Defendant promptly appealed from the interim order and applied to the Court of Appeals for such stay. The stay was granted by order made by the Court of Appeals on December 13, 1971.[21/]

The taking of testimony by this Court had begun on June 7, 1971, and had continued intermittently through November 8th when an order was filed by the Court directing that the hearing on plaintiff's application for a preliminary injunction be consolidated pursuant to Fed. R. Civ. P. 65(a)(2) with the trial of the action for a permanent injunction. Thereafter the trial continued on an almost day-to-day basis and was still in progress when decision comprising the findings and order granting the preliminary injunction was signed on December 8th. These findings were based on the proceedings and testimony through November 29, 1971. What is set forth in the opinion of November 11th, 1971, and these later findings, conclusions and order will not be here repeated, being deemed

incorporated in this opinion by reference.

Inasmuch as the appeal was taken only from the interim injunction order, the ongoing trial the outcome of which would be either a permanent injunction or a final judgment for the defendant went forward notwithstanding such appeal.

However, with 10,000 and more pages of testimony in this Court and in the Connecticut trial and with hundreds of exhibits in both trials to serve as a base for its final determination and with defendant pointlessly using up court time in supplying cumulative testimony through an endless stream of unimportant witnesses, this court on November 29th declared the trial for a permanent injunction closed for the reception of further evidence and set up a schedule for the filing of briefs.

With the stay of the interim injunction lifted by the December 13th order of the Court of Appeals, however, this Court of its own motion on January 6, 1972, reopened the trial to enable the defendant to offer additional testimony which the Court's closing of the evidence on November 29th might have precluded it from presenting. Further sessions of the Court for the hearing of defendant's witnesses were thereafter held on February 1st, 2nd, 3rd, 4th and 10th at which point both sides rested.[22/]

With the conclusion of the testimony nothing was sharpened, nothing was changed, except that the Court no longer felt by its imposed termination of the trial on November 29th it might have shut out something of importance which the defendant had to offer. It was now clear that defendant had had nothing to add.

On March 20, 1972, the Court of Appeals affirmed this court's preliminary injunction, United States v. Diapulse Corporation of America, 457 F.2d 25 (2d Cir. 1972). The opinion added little, if anything, to what had been earlier said by it in its affirmance of the Connecticut district court and what Judge Blumenfeld had written in that [illegible] and what this court had enunciated in its grant of the preliminary injunction.

"The Food, Drug, and Cosmetic Act has as its purpose," the Court of Appeals declared,

> "the protection of the public from products not proven to be safe and effective for their alleged uses and the safeguarding of the public health by enforcement of certain standards of purity and effectiveness. The reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction."

At a later point: "No specific or immediate showing of the precise way in which violation of the law will result in public harm is required."

BLEED THROUGH

Judge Rosling Decision, June 9, 1972

29.

As for exercise of judicial discretion in issuing and framing the terms of an inunction, the Court of Appeals declared:

> "The injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur."

In answer to the contention that the injunction was impermissible as calculated to put defendant out of business, the opinion's acerb comment was an excerpt from an earlier case that there "'can [be] no vested interest in a business activity found to be illegal.'"

In summation the Court of Appeals had this to say:

> "The device had been found to be generally misbranded, in violation of the statute, and in addition, a jury of laymen had found 49 specific claims to be false or misleading. Yet the company continued its brazen advertising scheme, failing to inform its buyers and lessors of the litigation or of the dispute in medical circles about the machine's efficacy. It did not prove the machine's effectiveness or relabel it to the FDA's satisfaction. The company's persistence in marketing the device makes it highly likely that the prohibited activity will cease only on the issuance of a blanket prohibition on shipment."

The argument had been advanced by appellant that this Court's requirement that the FDA approve the labeling as a condition for lifting the injunction imposed upon defendant an illegal "pre-clearance" restriction before the

device could be manufactured and shipped. In answer the Court of Appeals wrote:

> "The circumstances of this litigation make analogy to pre-clearance less than persuasive. Diapulse is not attempting to market the machine for the first time; on the contrary, a machine differing only in detail from present models has been condemned because the labeling was false and misleading. Corrective measures are required before the machine can be shipped in commerce. The court below found, following the order in the Connecticut action, that the FDA, the administrative agency charged with implementation of the statute which the company was found to be violating, was the best qualified to assess and formulate, with the company, labeling that is not false or misleading. The court itself is not expert on the medical and scientific issues which must be explored in order to produce accurate labeling; the assignment of that function to the FDA is sensible and proper. Cf. United States v. Allan Drug Co., 357 F.2d 713 (10th Cir. 1966). The order does not leave the company in doubt about what acts are prohibited or the methods by which it can proceed to correct its violations."

Finally, the opinion gave to this Court the recognition trial courts sitting without a jury are endlessly accorded of having the primary authority "'to judge of the credibility of the witnesses.'"

Nothing that followed the taking of the appeal has affected the mountain of testimony and findings that preceded, nor except for some brief observations will this Court undertake to add to what it has already written nor to what the Court of Appeals wrote in affirmance.

Defendant has sought to overwhelm the several courts which have toilsomely dealt with its claims and the expertise of its witnesses. To argue detail with defendant at this point is both impossible and uncalled for. To do so would, in fact, drop the government in the semantic pit which the defendant has planned and dug for it. The only sensible rejoinder is that having been adjudged guilty of substantial misbranding, the defendant must now affirmatively establish what, if anything, its device is good for.

The procedure whereby a district court defers to a government agency with special skills and facilities, permitting it to make factual determinations in limited areas, and, when made, to fit them into the Court's broader rulings is not unusual.[23/] The Court of Appeals has approved such procedure.

The use, moreover, by defendant of its advertising matter both before and after the roof caved in upon it in Connecticut evince at best an attempt to evade the effect of the adverse adjudication, and at worst a brazen -- (the word is that used by the Court of Appeals on its affirmance of this court, not this Court's) -- disregard of its obligations to the public in marketing a device which may have some medical value or, as is likely, represents no less than sheer quackery.

BLEED THROUGH

The appended footnote 24/ indicates how the type of advertising, now generally ascribed to "Madison Avenue" can mislead while pretending innocent compliance with judicial restraints.

Defendant's attempt to present the nondescript host of witnesses it called, some medical, some lay and some of less respectable professions, as outstanding research specialists is preposterous. The lay, half-educated individuals who administer the affairs of the defendant and of which one, Ross, has the chief proprietary interest,are on the showing made before this court, somewhat less than completely interested in pure scientific research as applied to the sole product which Diapulse purveys. If this were a negligence action with medical "experts" hired and feed by both sides, espousing diametrically opposed views on what does and does not ail a plaintiff -- an antilogy judicially often remarked upon -- the court would perforce shrug the matter off, leaving to the all-wise jury the assessment of medical credibility.

But when, as here, a swarm of witnesses have testified, and cross-questioning of some has elicited relationships and pecuniary involvements with the defendant which are incompatible with that complete material neutrality which is the hallmark of a medical research man and his findings, one must infer that defendant's case as a whole is at the very least suspect.

BLEED THROUGH

POOR COPY

One final observation is in order. The proof in this trial running to many thousands of pages and based on months of testimony was received by the Court more liberally than would have been the case had the Court known in advance the full scope of what it knew by the time the trial concluded. Res adjudicata was operative as to most of the issues when the Connecticut forfeiture was first adjudged. Only some major scientific discovery subsequently transpiring could have required the reopening of the issues, and even as to that the Court would have been constrained to assume that the FDA would take that into account in its consideration of any usefulness the device might have. But the fact is that nothing which has been shown by defendant upon the trial has in the slightest degree served to strengthen the position which it maintained in Connecticut with such notable lack of success.

It is the Court's conclusion that the temporary injunction issued by it on December 8, 1971, should now be made permanent.

The foregoing and the matters incorporated therein by reference constitute the findings of fact and conclusions of law of the Court. The government has submitted proposed findings of fact and conclusions of law. The defendant has not done so.

Each party shall have until June 26, 1972, to serve upon the adverse party proposed amendments to these findings and conclusions and a proposed judgment for signature by the Court, making the preliminary injunction permanent, and file the same with the Court on or before June 30, 1972, thereafter.

U. S. D. J.

FOOTNOTES

1/ See Act § 201(h), 21 U.S.C. § 321(h) for definition of term "device."

2/ It is so classified by the Food and Drug Administration, ["FDA"].

3/ Judgment of forfeiture of a single machine was signed by District Court Judge Blumenfeld on March 31, 1967, after a verdict by a jury which rendered a general verdict of misbranding and answered affirmatively specific interrogatories as to misrepresentation in 49 instances as to diseases and conditions. No answer was made by the jury as to the remaining 68 diseases and conditions submitted to it. Judge Blumenfeld instructed the jury that if it returned a verdict of misbranding it was not "to go through the vast list of 120 [sic] and deliberate upon each one, but go to those -- if you reach them at all, which, in your view, represent the heart of the claims that were made * * * and pass only upon those * * *."

Following entry of judgment Judge Blumenfeld upon application of Diapulse entered an order on April 25, 1967, giving it an opportunity to relabel the device to bring it into compliance with the law, subject to and evidenced by the approval of the FDA pursuant to Act § 304(d), 21 U.S.C. § 334(d) (Supp. 1965). Such approval, as noted, p. 25, supra, has not been obtained. Thereafter the Diapulse corporation moved for judgment notwithstanding the verdict and for a new trial. Judge Blumenfeld denied the motion, 269 F. Supp. 162, decided May 24, 1967.

The Connecticut case was in this posture when the appeal to the 2d Circuit Court of Appeals was taken by the Diapulse corporation. After the affirmance by that court on January 30, 1968, 389 F.2d 612, the instant suit was begun in the Eastern District of New York by the filing of the complaint on April 25, 1968. Shortly thereafter on June 10, 1968, the Supreme Court denied certiorari, 392 U.S. 907, 88 S. Ct. 2059.

4/ i.e. without the appendices.

BLEED THROUGH

POOR COPY

5/ As will shortly appear, the Court of Appeals had already affirmed the Connecticut district court's determination on January 30, 1968, several months before suit was started in this court and all that remained was for the Supreme Court to deny certiorari which it did on June 10, 1968, less than four weeks after the answer was filed herein.

6/ The second and third defenses are frivolous. The first defense is not far behind. See in particular footnote 2.

7/ Procedure requiring such removal for trial to "a district of reasonable proximity to the claimant's principal place of business" unless the parties otherwise stipulate is provided for in Act § 304(a), 21 U.S.C. § 334(a), as then and presently in force.

8/ United States v. An Article of Device * * * Impulse Manufacturing Corporation of America, 389 F.2d 612 (2d Cir. 1968).

9/ "A drug or device shall be deemed to be misbranded -- (a) If its labeling is false or misleading in any particular."

10/ "§ 334. Seizure -- Grounds and jurisdiction

> (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *."

11/ Act § 304(d), 21 U.S.C. § 334(d) as then applicable and currently in force reads:

BLEED THROUGH

POOR COPY

"Disposition of goods after decree of condemnation

"(d)(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond."

12/ Pursuant to Fed. R. Civ. P. 50(b) and 59.

13/ Judge Blumenfeld's opinion contains a comment which illuminates the possibilities open to a cunning purveyor of misrepresented worthless, or worse, pseudo-therapeutic devices, of endlessly delaying and thus defeating the government's efforts to put a merited quietus to his activities. Judge Blumenfeld writes (p.168 id.):

> "Thus, the interrogatories were designed to protect the claimant who is now objecting. A second benefit from the interrogatories is the protection they give to both parties. The bases of the jury's verdict, thus particularized, permit the accurate review of both the sufficiency of the evidence and the propriety of its admission.
>
> "But to secure these advantages, it was not necessary to require either a 'yes' or a 'no' to each claim. This would have required the

BLEED THROUGH

POOR COPY

jury to deliberate for days, perhaps even longer. The temptation would be great for purveyors of misbranded products to make literally thousands of spurious claims; of necessity, the Government in seeking condemnation would not realistically be able to present evidence on so many claims, or if it did, the jury would be unlikely to remember all of them. Since the burden of proof rests on the Government, e.g., United States v. 47 Bottles, supra, 200 F. Supp. 1; United States v. 11-1/4 Dozen Packages, 40 F. Supp. 208 (W.D.N.Y. 1941), a jury would perforce have to find for the claimant on those claims which it could not remember, or on which the Government, because of the sheer mass of false claims, had not been able to present evidence. Thus, at the cost of sacrificing one device or sample of a product because only a few of the misbranding claims were found proved, a claimant would have obtained a judgment constituting a bar to any future action against all the rest of its devices on the remaining claims, spurious though they may be.

"The jury was not required to answer all of the interrogatories."

14/ This holding of the Court of Appeals was consistently ignored by Diapulse's counsel in the trial before this court, with iterated disclaimers of the labeling effect of literature which it continued with reckless disregard of content and no or inadequate warning to the recipients to sponsor and circulate as a promotional ambience for the sale of its device.

15/ Similar testimony was received by this Court in the early stages of the trial when it was endeavoring to familiarize itself with the scope of the proof it was to receive before it had had an opportunity, since availed of, to read the 2,000 plus pages of Connecticut trial record and to assess the res adjudicata effect of the judgment rendered by that court.

16/ Misbranding carries with it criminal penalties of fine and imprisonment under 21 U.S.C. § 333 and, if an injunction against disposition were granted, violation of the injunction would, of course, expose the contemnor to civil and criminal punishment for the contempt.

BLEED THROUGH

POOR COPY

17/ Judge Mishler had on the same day signed a temporary restraining order against the Diapulse corporation enjoining it from introducing into interstate commerce any similar device, assembled or unassembled, bearing or accompanied by leaflets, brochures, etc. that said articles are an adequate and effective treatment for the 49 diseases, disorders and bodily conditions as to which the Connecticut jury had reported affirmatively that there had been misrepresentation.

The temporary restraining order was directed to expire by May 9, 1968, unless otherwise ordered by the Court and hearing on the application by the government for a preliminary injunction was set down for May 6, 1968.

18/ It appears that the same affidavits were submitted in support of the temporary restraining order (Golden and Everline, sworn to April 24, 1968, and Eastwood, April 16, 1968) as were presented as a basis for the preliminary injunction.

In opposition to the temporary restraining order defendant submitted only the single affidavit of its president, Jesse Ross. It is clear that the thrust of the government's applications for a temporary restraining order and an interim injunction was the claim that after the entry of judgment in Connecticut on March 31, 1967, inspectors of the FDA had found "samples of the device and accompanying labeling making the same claims as those adjudged false in the seizure action to have been shipped by the defendant to various distributors and purchasers across the country," (Carl Golden affidavit, p. 2) and that as recently before the applications for injunctive relief as April 5, 1968, the manufacturing and distribution operations of the company were being expanded.

While technically the Connecticut condemnation and restraint was directly limited to the single machine which had been seized, defendant plainly understood that the Diapulse company and its chief officers, personally, were amenable to criminal sanctions should Diapulse continue to sell or lease its product with similar labeling.

It was no doubt fear of such penalization which prompted Ross in his affidavit to limit his opposition to a denial of "the impression" which the government sought to create "that the defendant shipped the machines to Illinois, Portland, Oregon and Wichita, Kansas, accompanied by literature making some or all of the 49 claims as to which the jury in its special verdict answered 'yes'."

BLEED THROUGH

POOR COPY

19/ Note the complete absence of any suggestion that the adjudication was an adverse one of sweeping misrepresentation by Diapulse of the therapeutic efficacy of its device, to say nothing of the criminal and contempt sanctions to which the further distribution of the misbranded device implicitly exposed the company and the individuals who were its confederates in wrongdoing. Nor was the preliminary injunction order circulated in its complete form. The part of the order distributed with the letter omits all the pejorative introductory recitals, including the judgment of misbranding filed in Connecticut March 31, 1967.

20/ Note how shrewdly the author of the letter converts a complete judicial restraint by reason of major misrepresentations, possibly tainted with fraud, into an implied approval by the court that the device is beneficial in the treatment of many diseases. Note also the suggestion that no more is involved in the government's intransigent prosecution of a major offender than a friendly disagreement with a government agency as to the effect of "applicable rulings."

21/ The appellate court's order provided for an expedited appeal.

22/ Although defense counsel had urged vigorously upon the Court before the hearings were scheduled that defendant had a host of professional witnesses to be called whose testimony was crucial, the host never materialized and the volume of testimony for which full days of court time were scheduled speedily dwindled into a trickle of generalizations and repetitions of unimportant clinical observations by equally unimportant witnesses. It appeared to the Court when defense counsel announced on February 10th that he rested, that it was with a sense of relief that he did so.

23/ In Re Scranton Corp., 235 F. Supp. 770, 774, 775 (M.D. Pa. 1964). Cf. Best v. Humboldt Placer Mining Co., 371 U.S. 334, 83 S. Ct. 379 (1963); Thompson v. Magnolia Petroleum Co., 309 U.S. 478, 60 S. Ct. 628 (1940).

24/ A half century ago Dr. Royal S. Copeland, a physician who was also senator from the State of New York conducted an innocuous and indeed, instructive radio program in which he

BLEED THROUGH

POOR COPY

spoke briefly on medical topics in orthodox fashion. The Court recalls tuning in one day and hearing the great doctor speak of cancer of the stomach in modulated tones and with content wholly sincere and unexceptionable. Moments after he had concluded, however, the quack of the day could be heard broadcasting, in the program immediately following, the pitch for his particular health food. This, he blatantly proclaimed, if diligently ingested would by dietary mumbo jumbo shoo away the nasty carcinoma. The collocation of programs may have been an innocent one, but their synergistic effect on the troubled listener was manifest.

This is a crude illustration of how one may advertise without seeming to. Where, as here, defendant asserts that it can "plug" as therapeutic what has not been literally and expressly forbidden, it is clear that if it is to be permitted to sell its device again, it should concomitantly be well supervised and for an extended period be required to publicize the adverse findings of the courts as to its product and its own contrition at the misinformation it has diffused as part of its merchandising in the past.

Decision, November 11, 1971, Rosling, J.
Granting Motion for Preliminary Injunction

1.

NITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
- - - - - - - - - - - - - - - - - -x
NITED STATES OF AMERICA,

laintiff,

-against- 68-C-391

DIAPULSE CORPORATION OF AMERICA
also known as THE DIAPULSE
MANUFACTURING CORPORATION OF
AMERICA, a corporation,

efendant.
- - - - - - - - - - - - - - - - - -x

NOV 1 1 1971

Appearances:

ROBERT A. MORSE, ESQ.
United States Attorney
Eastern District of New York
Attorney for Plaintiff

Cyril Kyman, sq.
ssistant U. S. Attorney
Of Counsel

BASS & ULLMAN, SQS.
Attorneys for Defendant

Milton Bass, Esq.
Of Counsel

ROSLING, J.

aving several days earlier made an oral motion for a preliminary injunction pursuant to Fed. R. Civ. P. 65, the Government, ursuant to the direction of the Court on Friday, November 5, 1971, oved at the opening of court on papers without return date for the relief it sought by oral applica-

BLEED THROUGH

POOR COPY

tion. The Court originally directed that the motion be heard on November 9th but when the defendant before the end of the November 5th morning session announced that it would have no further witnesses available until Monday, ovember 8th, the Court directed that the Government's motion be orally argued during the afternoon session of the 5th at 3:?0 P.'.

ollowing the argument, which was held as directed, the Court ordered that the preliminary injunction prayed for issue, nd further, that in conformity with Fed. R. Civ. P. 65(a)(2), the ongoing evidentiary hearing on the Government's application for a preliminary injunction be consolidated with the trial of the action on the merits which the Court advanced for the purposes of such consolidated hearing and trial.

ime pressures prevent the inclusion in this opinion of a complete statement of facts and proceedings. Incorporated herein to the extent reported are those stated in United States v. An Article of Device * * * Diapulse Manufacturing Corporation of America, 269 F. Supp. 162 (D. Conn. 1967, Blumenfeld, ".J.) and affirmance of the judgment by the Court of Appeals of the circuit, 389 F.2d 612, decided January 30, 1968. Certiorari was denied, 392 U.S. 907. The effect of such judgment had been to hold that a typical Diapulse machine, the sole product of the company, except for a boundless distribution of literature which Diapulse circulated and which was held to constitute the

BLEED THROUGH

labeling of the device, had been misbranded generally, and misrepresented specifically as to 49 diseases, disorders and conditions within the intent of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq.

The single machine involved in the Connecticut case had been seized in an in rem forfeiture proceeding together with its sheaf of brochures, testimonials, etc., from the possession of a Georgia chiropractor who presumably used the machine in his practise. The suit was transferred to Connecticut where the Diapulse company undertook the direct defense and lost catastrophically.

The libel of information filed in December, 1965, had charged that the device, a pulsed high frequency generator similar to a conventional diathermy unit but with a lower output, had been misbranded in that it was represented by Diapulse in the literature referred to to be adequate and effective for the treatment of some 121 different diseases and related conditions. The misbranding rested upon the Government's claim that these representations were false and misleading.

The issue was submitted to the jury in Connecticut for the rendition of a general verdict and, if rendered for the Government, for affirmative answer as to enumerated diseases,

BLEED THROUGH

..isorders and conditions, 117 in number as to which false or misleading claims were made. Judge Blumenfeld was clear in his instruction to the jury given in the course of his charge that they were not required "to go through the vast list of 120 and deliberate upon each one, but go to those -- if you reach them at all, which, in your view, represent the heart of the claims that were made * * * and pass only upon those. * * *."

The jury with a noteworthy diligence actually answered in the affirmative as to 49(!) of the diseases and conditions, a fantastically large number for a group of laymen. The scope of the misrepresentations so found to have been made may be dimly apprehended from a random selection of a half-dozen of the diseases for which the device was touted as a therapeutic adjunct to other treatment or even as primary treatment. Included in the list are infections, systemic diseases, abdominal and pelvic pain and tenderness, ulceration, ear conditions, and hypertension and upper respiratory infections in children.

The individual, Jesse Ross, heads the defendant corporation, an international enterprise, never completed his education at college level, and appears to be a promoter, salesman and public relations expert rather a person with a professional background, in particular medical or scientific.

BLEED THROUGH

POOR COPY

Decision, Nov. 11, 1971, Rosling, J.

Judge Blumenfeld in his opinion (p. 168) commented that "[c]laimant mistakes the purpose of a court. It is not a pharmaceutical testing house. The machine was condemned pursuant to statute, and that finding of condemnation occurred when the court accepted the jury's verdict in its general form * * *."

Judge Blumenfeld had upon claimant's motion, by order made April 25, 1967, following the entry of judgment of forfeiture on March 31, 1967, made a direction under 21 U.S.C. § 334(d) (Supp. 1967) (Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeiture)[1/] for relabeling of the device so as to bring it "into compliance with the Federal Food, Drug and Cosmetic Act" upon fulfillment of certain conditions expressed in the statute. The chief of these was that the forfeited machine should be submitted to the Department of Health, Education and Welfare for the receipt of directions as to what was required to bring the machine into compliance.[2/] The record is unclear as to what attempts, if any, were made to comply with this and other provisions of the order of April 25, 1967, and which at best appear to have been tentative only and proved abortive.

The Court of Appeals in its opinion on affirmance of Judge Blumenfeld was precise in its approval of the procedure he outlined in his order, writing (p. 715):

BLEED THROUGH

POOR COPY

Decision, Nov. 11, 1971, Rosling, J.

6.

"It is argued that because there was a general judgment, and it is not clear what the jury specifically found, appellant will not be able to properly relabel its product. As Judge Blumenfeld said: 'Claimant mistakes the purpose of a court. It is not a pharmaceutical testing house.' Admittedly it would be easier for the claimant in an action such as this to go forward with relabeling its product if the judgment were more specific, but the purpose of the action is simply to condemn the drug, machine, etc. if misbranded (see discussion above), and the action is provided for by statute. The initial determination of the legality of the new labeling is for the administrative body." [underscoring supplied. The administrative body is, of course, the Food and Drug Administration which is a division of the Department of Health, Education and Welfare.]

Defendant now chose a desperate and reckless course. The course would have been dangerous even if Diapulse's subsequent conduct were being inscribed on a clean slate, but with its history of major misrepresentation to poison the atmosphere in which it projected its torrent of sales talk, it chose suicidally to exploit its device as of therapeutic value wherever the special findings of the jury had left untouched by its affirmative hostile determination a crevice or cranny not specifically adjudicated.

Judge Blumenfeld's opinion spoke discerningly of defendant's obvious scheme to bury the Government beneath a mountain of spurious claims of ailments and conditions allegedly benefited by the use of its device which the Government, even through a maximum effort directed toward

BLEED THROUGH

POOR COPY

disproof, could only partially meet and oppose. The opinion speaking of the fact that the jury had reported on only 49 of the 117 claims reads in pertinent part as follows (p. 168):

> "But to secure these advantages, it was not necessary to require either a 'yes' or a 'no' to each claim. This would have required the jury to deliberate for days, perhaps even longer. The temptation would be great for purveyors of misbranded products to make literally thousands of spurious claims; of necessity, the Government in seeking condemnation would not realistically be able to present evidence on so many claims, or if it did, the jury would be unlikely to remember all of them. Since the burden of proof rests on the Government, e.g., United States v. 47 Bottles, supra, 200 F. Supp. 1; United States v. 11-1/4 Dozen Packages, 40 F. Supp. 703 (W.D.Mo., 1941), jury would perforce have to find for the claimant on those claims which it could not remember, or on which the Government, because of the sheer mass of false claims, had not been able to present evidence. Thus, at the cost of sacrificing one device or sample of a product because only a few of the misbranding claims were found proved, a claimant would have obtained a judgment constituting a bar to any future action against all the rest of its devices on the remaining claims, spurious though they may be.
>
> "The jury was not required to answer all of the interrogatories."

Had the Government chosen at this juncture when the Georgia chiropractor's Diapulse contraption was by judgment filed March 31, 1967, declared forfeited for the grossest sort of misbranding, to seize the entire inventory of defendant for similar forfeiture and moved for injunctive relief against any further deception of those purchasers who were innocent of complicity and restraining those others who were particeps

BLEED THROUGH

POOR COPY

criminis under Fed. R. Civ. P. 65(d) from foisting the therapeutic use of the device upon a gullible public,[3] the motion should have been granted.

This conclusion follows from a number of considerations: the fact that the forfeited machine did not differ in principle, but only in unessential detail, from the single later model[4] which defendant marketed; whatever literature accompanied the machines disposed of by defendant at the time of disposition or later up to the date of the judgment continued at least to some time in the following year, 1968, to emanate from defendant with certain documents being withheld for reasons other than the possible falsity of the representations contained therein. The fact that the judgment was not affirmed until January 30, 1969, did not at all detract from the res adjudicata effect of the March 17, 1967 judgment.

The Government, however, did not bestir itself until April 25, 1968, when it filed the complaint for injunction in this court which we are presently trying. Central allegations in said complaint are the following:

> "5. In the interstate sale and distribution of said device, the defendant has utilized a number of items of written, printed, and graphic matter which comprise the labeling of said device, including leaflets containing directions for use, leaflets containing instructions, warranty brochures, [illegible] brochures, [illegible] advertisable layouts, reprints of speeches, and reprints of published articles.

BLEED THROUGH

POOR COPY

Decision, Nov. 11, 1971, Rosling, J.

9.

6. In the promotion of the interstate sale and distribution of said device, the defendant organizes symposia, sponsors meetings and has exhibits and sales representatives at meetings of osteopaths, chiropractors, and physicians at which false and misleading representations are made orally and in labeling as to the mechanism of action of the said device and the effectiveness of the device in the treatment of disease and in affecting the functions and structure of the human body.

7. Said defendant has repeatedly promoted the device with additional false and misleading claims for said device.

8. The defendant has not corrected or repudiated any of the claims or representations in the labeling referred to in paragraphs 5 and 6 above.

* * *

11. Forty-nine claims used in the promotion of the device have specifically been adjudicated as false and misleading, and a general verdict and judgment of misbranding has been entered, in prior litigation between the United States of America and said Diapulse Corporation of America, in the District of Connecticut and the Court of Appeals in the Second Circuit, United States v. An Article of Device * * * Diapulse, (D. Conn. Admiralty No. 4818, 1967) aff'd ___ F.2d ___ (Docket No. 31720 C.A. 2, Jan. 30, 1968) and that adjudication is final and conclusive against Diapulse Corporation of America, in this action. Notwithstanding this adjudication, defendant has not corrected or repudiated any of the above claims or representations but in fact has continued to make and use them."

From the somewhat lengthy prayer for relief the following items demanded are quoted for the light they throw upon the issues. These items the court has found to be of paramount significance in its evaluation of the issues. They ask:

BLEED THROUGH

POOR COPY

"That the defendant and its officers, agents, employees, representatives and all other persons in active participation with it be perpetually enjoined from introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, said device or any similar device with any claims whatever as to the device's effectiveness or mode of action in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animal, unless and until the said defendant assembles the scientific evidence on which the relabeling of the device is to be based, the defendant prepares revised labeling in full conformity with the Federal Food, Drug, and Cosmetic Act and regulations thereunder, specifically 21 C.F.R. 1.106, and the defendant submits such scientific evidence and revised labeling to the Food and Drug Administration and obtains approval thereof.

"That the defendant be ordered to give written notice, in a form approved by this Court, of the provisions of the prior adjudication and of this Court's decree of Injunction to each and every person known to the defendant to have purchased, leased, or have in his possession a Diapulse device and to the officers, agents, and employees of the corporation and to each and every person who has been or is a distributor of the Diapulse device or a sales representative for this device and to all persons now and in the future in active concert or participation with said defendant, assisting or participating in the sale or manufacture, or promotion of said device or any similar device;"

Defendant's denials of the paragraphs quoted are to some extent qualified, but may to all intents and purposes be treated, as they are, as a general denial of the material parts of what is alleged.

Service of the complaint was admitted by the present attorneys[5/] for the defendant on April 25th, the day the pleading was filed.

BLEED THROUGH

POOR COPY

Decision, Nov. 11, 1971, Rosling, J.

11.

On April 26, 1968, the Government submitted to Judge Mishler an order to show cause why a preliminary injunction should not issue. Inasmuch as the proposed show cause order contained a TRO the Court conducted a hearing on the same day and on April 29th signed the TRO applied for. The motion for a preliminary injunction was made returnable on May 6th by the order to show cause.

An order granting a preliminary injunction was signed by Judge Mishler on May 2, 1968. It had been agreed to by defendant. The injunction recited the judgment of misbranding of March 31, 1967, and the fact that "Defendant agrees to the issuance of a Preliminary Injunction * * * for [the] purposes of effectuating an orderly procedure pending trial and determination of this action and without admitting the allegations of fact or law set forth in the Complaint filed herein; and upon the Consent of the defendant, annexed hereto * * * [.]"

The ordering paragraphs of the injunction, quoted in full in the footnote,[7/] barred the disposition of all of defendant's machines and literature upon representations of medical usefulness in the treatment or alleviation of the 49 diseases, purposes or conditions as to which the jury had affirmatively reported it found false or misleading claims had been made by defendant's labelling.

BLEED THROUGH

POOR COPY

It is a fair inference that defendant's readiness to consent to the preliminary injunction was only in part the consequence of its recognition of the defeat it had sustained in Connecticut and of its continuing misrepresentation thereafter of the therapeutic benefits to be derived from the use of its machine. The chief reason for defendant's complaisance, it would appear, was a realization that the restraint on its offending activities could no longer be staved off, and that evasion by a pretended compliance with the Connecticut decree applied in spirit to its entire output was to be the order of the day. Broadly stated, defendant's position was to be that any representation that the jury had not affirmatively reported as a misrepresentation was to be deemed to have received a cachet of approval for the continuance of the representations as to the diseases and conditions concerning which the jury in conformity with the Court's instruction had given no answer.

In implementation of this misconstruction, innocent or designed, of the judgment, Jesse Ross, abetted by defendant's sales manager, Mr. Siler, drafted a letter dated May 6, 1968, a copy of which is set out in the appended footnote.[8/] This was circulated among defendant's dealers from whom it thereafter made a half-hearted effort to retrieve some of its offending literature earlier distributed. The medical and sundry pseudo-medical practitioners of the therapeutic art were left to wallow in their morass of misinformation, as were the patients who were

BLEED THROUGH

POOR COPY

to be induced to receive the supposedly beneficial treatments in the future.

Some of the literature was edited or excerpted before being recirculated to conform with the Ross-Miller theory of what they could do without being in violation, and new brochures, news letters and instruction sheets were passed around by Diapulse among those who might be induced to buy the machine. However, even if defendant's surmise as to the limited reach of the Connecticut defeat were valid, the vast areas of human disease and even malaise encompassed by the 49 affirmative findings were such that little more than the Moldavian Crud, a mythical ailment of unknown etiology and symptoms and not found in any medical dictionary, to which this Court on occasion in the course of the hearings alluded, remained open to the defendant for adjunctive healing by the "ætherial" electromagnetic emanations of its device.

How could defendant escape the farflung net cast by an inhibition against undertaking to treat infections or low back pain and syndrome or systemic infections or pelvic inflammatory disease, abdominal pain and tenderness, or ulceration or ear conditions or severe itching or adrenal malfunction or hypertension and upper respiratory infections in children or staphylococcus infections, or stimulating the liver and spleen for therapeutic benefit? And if one could

BLEED THROUGH

POOR COPY

By some fancy broken field running escape these semantic linebackers, is it possible that he could also get by an injunction which barred him from "the safe treatment of the entire patient," or "stimulating tissue responses and the natural defense mechanisms of the body" or from "stimulating the patient's own repair mechanism which frequently achieve results where other forms of treatment have failed" or from "restoring good health"(11) or "'perking up' sick and run-down cells of the body with new life and fresh vigor" or "re-energizing the human mechanisms" or "giving results where all else has failed?"

After both sides wasted in largely needless pretrial proceedings the years since April 25, 1968, when the action was commenced, the court, under pressure from above to bring the calendars up-to-date and estimating that this case had been largely decided in the Connecticut litigation, pushed the parties into beginning on June 7, 1971, the evidentiary hearing on the general preliminary injunction with possible consolidation of the trial of the permanent injunction on the merits pursuant to Fed. R. Civ. P. 65(a)(2). This hearing was continued on June 8, 9, 10, 11, 14, 15, 16, 17, 21 and 22 and then carried over to the fall to October 12, 13, 14, 15, 18, 19, 20, 21, 22, 27 and 28, and November 1, 2, 3, 4, 5, 8, 10 and 11. The Court's purpose, among others, in directing the long adjournment over the summer was to afford defendant an opportunity, if it chose to avail itself of it, to complete its

BLEED THROUGH

POOR COPY

readiness for its part of the trial. It is not clear, as the incidents of trial confirm, what substantial proof, not utilized by the defense in Connecticut, could be collected by the defense during the summer recess.

On Friday, ovember 5th the Government moved on papers for what is in effect an extension of the preliminary injunction to which defendant, as noted above, consented and the order for which was signed by Judge Mishler on May 2, 1968.

he defense began the introduction of testimony on October 28th and it was at once apparent that, despite warnings given by the court against such practice, defense counsel were bent on recalling as witnesses the same persons who had testified with scant success in Connecticut to give the same testimony here that they had given there with unessential supplementation. Although the defense had, moreover, at some earlier stage of the trial or possibly before its commence- ent threatened to call some sixty or possibly one hundred sixty witnesses, efense appears to have reduced that number to six or less witnesses, several of whom have already testified. pportunity has also been given defendant by the Court to make offer of proof as to what the remaining witnesses will testify to.

It is clear, as the Court has several times reminded the attorneys, that months will elapse before the slow moving

BLEED THROUGH

POOR COPY

attorneys complete the defense and rebuttal, the ten or more thousands of pages of record and exhibits before this Court are transcribed by the reporter and proofread by the Court, the briefs of the parties are prepared and submitted with the four or five hundred exhibits[9/] and the Court sweats over the bushelbasketful of papers before it comes up with its decision. In such context of circumstance it was imperative that the Court issue at once the long delayed preliminary injunction which would take defendant's nontherapeutic device and its welter of intermingled true, half-true, and false promotional material out of the mainstream of medicine and without the Courts awaiting the lethargic progress of the hearings to run its course. The interim injunction it now issues could be later modified and limited in the unlikely event that some proposed changes in defendant's marketing procedures, including defendant's dropping of its claims to the athermal[10/] functioning of its machine, take place.

It is no answer for defendant to urge upon the Court that the Government establishes no irreparable damage from defendant's continued marketing of its machine. As a public agency the F.D.A. is obligated to protect the public even from its own folly and the statute itself which Congress enacts in the public interest is grounded on the assumption of such public harm from its violation.[11/]

BLEED THROUGH

POOR COPY

Nor can defendant find support for its position in the circumstance that in the spate of literature which inundates the medical profession in an overwhelming flood it is able to find some scientific or pseudoscientific voices which by their claims create a climate of differing views and medical opinion as to the effectiveness of defendant's device. It was the very failure on defendant's part to reveal this "material difference in scientific opinion" as to the merits of the device that led Judge Blumenfeld to charge his jury and the jury to find misrepresentation as to the efficacy of the device in such silence.[12/]

Nor, finally, is the Court to measure the scope of its injunctive restraint by exact congruence with the area of violation heretofore engaged in. The equitable rule and its corollaries are too well understood to require citation of authority that injunctive relief can be as broad as is necessary to inhibit unlawful action which it appears, under all the circumstances of past conduct whether persisted in or already abandoned, is likely to recur.

The Court's decision that a preliminary injunction issue was announced from the bench as tentative and subject to the opinion of the Court which would be written over the weekend. The Court simultaneously ordered under Rule 65(a)(2) that the trial of the action on the merits be consolidated with the hearing of the application for a preliminary injunction.

BLEED THROUGH

POOR COPY

The parties were, accordingly, directed to proceed with the hearing and trial on Monday, November 8, 1971. So that the record on both aspects of the ongoing proceedings may be complete at the successive terminal points when, respectively, the order for a preliminary injunction is about to be signed by the Court, and when much later the judgment on the action is similarly to be signed after all live testimony and other proof shall have been adduced by the parties, the Court requires the attorneys for the defendant to complete the defense they choose to offer to the motion for a preliminary injunction by making a formal offer of proof as to any evidence which in the view of defendant remains to be presented before this opinion has been filed and the order for a preliminary injunction signed, provided, however, that defendant shall have introduced by formal testimony of live witnesses, exhibit or stipulation the same evidence in the course of the continuing trial of the action for a permanent injunction as to which an offer of proof is now to be made. Defendant, of course, may in the trial of the action offer additional proof, if competent, in other areas and by other witnesses. Let a preliminary injunction issue, pursuant to the foregoing, the order to be submitted by plaintiff on five days' notice of settlement to defendant.

GEORGE ROSLING

U.S.D.J.

BLEED THROUGH

POOR COPY

FOOTNOTES

21 U.S.C. § 334(d):

"Disposition of goods after decree of condemnation

"(d)(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 331(d) of this title can and will be met: Provided, however, That the provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title: And provided further, That where such exportation is limited to the original foreign supplier, then clauses (1) and (2) of section 381(d) of this

BLEED THROUGH

title and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(d) of this title have been met. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

"(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

"(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to depressant or stimulant drugs or counterfeit drugs."

The order provides that

"3. The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare shall have had free access thereto in order to take any sample or make any tests or examinations that are deemed necessary, and shall in writing have released such article for shipment, sale, or other disposition."

BLEED THROUGH

POOR COPY

3/ An order granting an injunction and every restraining order binds under subd. (d) of Rule 65 not only the parties to the action, but also "their officers, agents, servants, employees, and attorneys, and * * * those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise."

4/ The Connecticut machine was Model #101. The only other model defendant sold or otherwise distributed was #102.

5/ The attorneys, Bass and Friend, had tried the case in Connecticut for the defendant.

6/ Plaintiff's motion for a preliminary injunction returnable May 6, 1968, was withdrawn.

7/ "IT IS ORDERED that plaintiff's motion for Preliminary Injunction returnable May 6, 1968 be and the same hereby is withdrawn; and

"IT IS FURTHER ORDERED that the defendant, Diapulse Corporation of America, a corporation, and each and all of its agents, servants, employees and representatives, and all and any persons in active concert or participation with it be and they hereby are restrained and enjoined pending trial and determination of this action from directly or indirectly causing any of the following acts with respect to articles of device known as Diapulse, or any similar articles of device:

"A. Causing to be introduced or delivered for introduction into interstate commerce any of said articles in whole or in part, assembled or unassembled, which:

1. Bears or is accompanied by any item of written, printed, and graphic matter, such as leaflets containing directions for use, leaflets containing instructions, and warranty brochures, advertising brochures, advertising layouts, reprints of speeches, and reprints of published articles, which contain statements and representations that directly or indirectly refer, represent, suggest, or create the

BLEED THROUGH

POOR COPY

impression that said articles are an adequate and effective treatment for any of the following purposes, conditions, and diseases:

Infections
Otitis media
Low back pain
Parietal and occipital headaches
Systemic diseases
Rheumatic fever
Reiter's syndrome
Hypersplenism
Undulant fever
Tuberculosis
Pelvic and inflammatory diseases complicated by adnexal masses
Abdominal and pelvic pain and tenderness
Diabetes
Diabetic ulcer of the foot
Occlusive vascular disease
Infection of lower extremity
Ulceration
Gangrene
Paresthesias in the form of numbness
Gonorrhea
Syphilis
Tularemia
Typhoid fever
Serum sickness
Other systemic infections
Osteoarthritis
Gout
Low back syndrome
Pelvic Inflammatory disease
Ear conditions
Vaginitis
Severe itching
Trichomonas vaginalis
Peripheral vascular insufficiency
Adrenal malfunction
Hypertension and upper respiratory infections in children
Staphylococcus infection
Septic sore throat

For the safe treatment of the entire patient.

For stimulating tissue responses and the natural defense mechanisms of the body.

To enhance and stimulate the reticuloendothelial system and for stimulating the patient's own repair mechanisms which frequently achieve results where other forms of treatment have failed.

Restoring good health.

'Perking up' sick and run-down cells of the body with new life and fresh vigor.

Re- nergizing the human mechanisms.

BLEED THROUGH

Increasing leukocytes and steroids in the blood without any contraindications.

tinulating of the liver and spleen.

Increasing antibody formation.

Increasing the anticenic reactivity of human gamma globulin.

or giving results where all else has failed.

. Is intended for delivery to any person whom said defendant has good cause to believe does or will represent by any means to prospective dealers, purchasers, renters, or lessees of said articles that said articles are an adequate and effective treatment for any of the purposes, conditions and diseases listed in A 1., above.

.. causing any act to be done with respect to any of said articles while any of said articles are held for sale after shipment in interstate commerce, which acts result in any such articles being misbranded in any of the ways specified in A 1 and 2 above."

Letter of May 6, 1968, from Diapulse to its franchisees as follows:

"TO ALL DEALERS AND DEALER SALESMEN

To avoid any misunderstanding, and to clarify the current status regarding the manufacture, shipment and sale of Diapulse units, please be advised as follows:

1. After lengthy litigation (which is still pending for consideration before the United States Supreme Court), a judgment was obtained by the Food and Drug Administration to the effect that 49 specifically enumerated claims, out of 121, may not be made for Diapulse units, directly or by implication.

Decision, Nov. 11, 1971, Rosling, J.

24.

72 CLAIMS, HOWEVER, WERE NOT RESOLVED IN FAVOR OF THE FOOD AND DRUG ADMINISTRATION.

On May 1, 1968, without admitting any of the allegations of fact or law as set forth in the complaint, they voluntarily agreed that an order be entered temporarily prohibiting the shipment or sale of Diapulse units with any of the 49 representations or suggestions, as shown in the attached order.

2. THE COURT ORDER DOES NOT AFFECT THE COMPANY'S RIGHT TO CONTINUE THE SHIPMENT, SALE AND SERVICING OF DIAPULSE UNITS, EXCEPT FOR THOSE CONDITIONS STATED IN THE 49 CLAIMS.

DIAPULSE MAY CONTINUE TO BE RECOMMENDED AS ADJUNCTIVE THERAPY IN THE TREATMENT OF THE FOLLOWING CONDITIONS, EXACTLY AS STATED:

one and Tissue Healing
Postoperative Wound Healing
Foot Ulcers
Venous Statis Ulcer
Gastric Ulcer
Fractures
Osteoporosis
Osteomyelitis
Increasing Peripheral Blood Flow without Hyperpyroxia
Peripheral Vascular Disorders
Sinusitis and allied conditions
Sinobronchial Disease
Bronchial Asthma
Lymphadenomis
Tonsillar abscess
Severe acne
Gynecologic disorders
Prostatitis
Bursitis
Calcified Bursitis
Arthritis
Radiculitis
Tennis Elbow
Whiplash syndrome
Smooth muscle spasm

3. To avoid any misunderstanding, and to assure complete compliance with all applicable rulings of the Court with respect to the purposes and uses of Diapulse in the treatment of various diseases,

BLEED THROUGH

POOR COPY

conditions and symptoms, you are to return to us immediately all literature, brochures and treatment charts with the exception of the following, which you may continue to use:

'Experimental Acceleration of Wound Healing,' Bruce H. Cameron, ...

'Peripheral Blood Flow Measurements During Application of Pulsed High Frequency Currents,' William James Erdman II, M.D.

'Congressional Record' (261-385-7904)

Further, no oral statements, representations, or suggestions shall be made which directly or indirectly, indicate, refer, represent, suggest, or create the impression that Diapulse is an adequate and effective treatment for any of the 42 purposes, conditions or diseases listed in the annexed order.

We are revising our treatment chart and literature in accordance with the foregoing, and will forward same to you as soon as they are available.

As always, it has been, and still is the company's policy to comply with all applicable rules and regulations concerning the sale and use of Diapulse. If you have any questions with regard to any of the above, please contact us immediately.

s/ Bern Siler
BERNARD O. SILER
GENERAL SALES MANAGER

.....Counsel for the respective parties having met and advised the Court that defendant agrees to the issuance of a Preliminary Injunction, as hereinafter set forth, for purposes of effectuating an orderly procedure pending trial and determination of this action and without admitting the allegations of fact or law set forth in the Complaint filed herein; and upon the Consent of the defendant, annexed hereto;

BLEED THROUGH

Decision, Nov. 11, 1971, Rosling, J.

IT IS ORDERED that plaintiff's motion for Preliminary Injunction returnable May 6, 1968 be and the same hereby is withdrawn; and

IT IS FURTHER ORDERED that the defendant, Diapulse Corporation of America, a corporation, and each and all of its agents, servants, employees and representatives, and all and any persons in active concert or participation with it be and they hereby are restrained and enjoined pending trial and determination of this action from directly or indirectly causing any of the following acts with respect to articles of device known as Diapulse, or any similar articles of device:

1. Causing to be introduced or delivered for introduction into interstate commerce any of said articles in whole or in part, assembled or unassembled, which:

1. Bears or is accompanied by any item of written, printed, and graphic matter, such as leaflets containing directions for use, leaflets containing instructions, and warranty brochures, advertising brochures, advertising layouts, reprints of speeches, and reprints of published articles, which contain statements and representations that directly or indirectly refer, represent, suggest, or create the impression that said articles are an adequate and effective treatment for any of the following purposes, conditions, and diseases:

Infections	Gonorrhea
Otitis media	Syphilis
Low back pain	Tularemia
Parietal and occipital headaches	
Systemic diseases	Typhoid fever
Rheumatic fever	Serum sickness
Reiter's syndrome	Other systemic infections
Hypersplenism	
Undulant fever	Osteoarthritis
Tuberculosis	Gout
Pelvic and inflammatory diseases complicated by adnexal masses	
Abdominal and pelvic pain and tenderness	Low back syndrome
Diabetes	Pelvic inflammatory disease

BLEED THROUGH

Diabetic ulcer of the foot
Occulisive vascular disease
Infection of lower extremity
Ulceration
Gangrene
Parasthesias in the form of numbness
For the safe treatment of the entire patient.
For stimulating tissue responses and the natural defense mechanisms of the body.
To enhance and stimulate the reticuloendothelial system and for stimulating the patient's own repair mechanisms which frequently achieve results where other forms of treatment have failed."

Ear conditions
Vaginitis
Severe itching
Trichomonas vaginalis
Peripheral vascular insufficiency
Adrenal malfunction
Hypertension and upper respiratory infections in children
Staphylococcus infection
Septic sore throat

9/ The minutes of the trial in the Connecticut proceeding, a single exhibit in this case, are over 2,000 pages in length.

10/ It is classified by the F.D.A. as a diathermy (thermal) device authorized to function on the same wave length as are the conventional diathermy machines, a recognition defendant chooses to reject.

11/ United States v. San Francisco, 310 U.S. 16, 31, 60 S. Ct. 749 (1940); Radford v. Securities and Exchange Commission, 278 F.2d 566 (9th Cir. 1960); Henderson v. Burd, 133 F.2d 515, 517 (2d Cir. 1943); American Fruit Growers, Inc. v. United States, 105 F.2d 722, 725 (9th Cir. 1939).

12/ See Judge Blumenfeld's opinion where he cites 21 C.F.R. § 1.3 (1967) as stating "without equivocation" that,

> "' he existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among

BLEED THROUGH

POOR COPY

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
- - - - - - - - - - - - - - - - - -x
UNITED STATES OF AMERICA,

Plaintiff,

-against- 68-C-391

IMPULSE CORPORATION OF AMERICA, a/k/a THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, DEC 8 1971

Defendant.
- - - - - - - - - - - - - - - - - -x

Appearances:

ROBERT A. MORSE, ESQ.
United States Attorney
Eastern District of New York
Attorney for Plaintiff

Cyril Lyman, Esq.
Assistant U. S. Attorney
Of Counsel

BASS & ULLMAN, ESQS.
Attorneys for Defendant

Milton A. Bass, Esq.
Of Counsel

Decision Constituting Findings of Fact and Conclusions of Law

ROSLING, J.

I

Plaintiff having moved for a preliminary injunction herein by notice of motion returnable on November 5, 1971,

BLEED THROUGH

and the papers, proceedings and evidence recited below having been before the court at the time of the signing of this order and having been found by the court a sufficient basis for the granting of such injunction, to wit:

1. Judgment entered March 31, 1967, in the United States District Court, District of Connecticut, Admiralty No. 3818, an in rem action, entitled, United States of America v. An article of device consisting of 1 device, more or less labeled in part: (metal plate on device) "Diapulse Serial No. 1824 Model D * * * Diapulse Manufacturing Corporation of America New York City" etc., copy of which judgment is hereunto annexed and incorporated by reference herein.

2. Order of the said district court, United States District Judge M. Joseph Blumenfeld, April 25, 1967 and filed on April 26, 1967, on a motion made by the Diapulse Corporation of America (hereinafter "Diapulse Corp.") to amend said judgment, copy of said order being hereunto annexed and incorporated by reference herein.

3. The affirmance on January 30, 1968, by the Court of Appeals of the Second Circuit of said judgment as so amended, on the appeal of Diapulse Corp. and the opinion of the Court of Appeals upon such affirmance (389 F.2d 612).

BLEED THROUGH

4. The denial of certiorari by the Supreme Court on June 10, 1968, 392 U.S. 907.

5. Following denial of certiorari defendant, on June 4, 1969, served a notice of motion returnable before Judge Blumenfeld, for an order further amending the amended Connecticut judgment by decreeing that the device had been brought into compliance with the law when labeled as being an adequate and effective treatment for tissue and bone healing, sinusitis, bursitis, arthritis and blood flow to peripheral areas. The notice of motion was endorsed in its margin on June 24, 1969, "Motion Denied." Said notice of motion and endorsement, copy annexed and incorporated herein by reference, are among the exhibits considered by the court as basis for the grant of a preliminary injunction.

6. The commencement of this action by the filing of the complaint against Diapulse Corp. on April 25, 1968, and the commencement of suit by the service of process on said Diapulse Corp. on April 25, 1968, and the pleadings in the action.

7. The service by plaintiff of an order made by a judge of the Eastern District of New York returnable May 6, 1968, to show cause why a preliminary injunction should not issue, the order made on May 2, 1968, by Chief Judge Mishler

BLEED THROUGH

of this court granting a partial preliminary injunction on consent of Diapulse Corp.

8. The testimony taken and exhibits introduced before this court upon an evidentiary hearing thus far held on the following dates in 1971:

Plaintiff's case: June 7, 8, 9, 10, 11, 14, 15, 16, 17, 21, 22; October 12, 14, 15, 18, 19, 20, 21, 22, 26.

Defendant's case: October 27, 28; November 1, 2, 3, 4, 5, 8, 9, 10, 11, 15, 16, 17, 18, 19, 22, 23, 24, 26 and 29.

9. The testimony and exhibits comprising the record of the in rem trial in Connecticut referred to in paragraphs "1" and "2" which were introduced by the Government as an exhibit in this case.

10. An order signed on November 8, 1971, by the court on its own motion pursuant to 28 U.S.C. § 65(a)(2), which consolidated the trial of the action with the hearing of the motion for a preliminary injunction.

II

The court estimates that the record of this trial and hearing, when fully transcribed, plus the exhibits will substantially exceed 10,000 pages. A minimum of six months will be required for the complete transcription and proof-reading of the minutes, the exchange and filing of briefs by the attorneys, the court's review of the transcript, exhibits and briefs, its independent research, and the drafting and filing of its opinion.

The foregoing considerations led the court, when a break in the trial on November 5, 1971, occasioned by defendant's temporary unreadiness to proceed with the production of witnesses provided the opportunity, to hear argument from counsel on the plaintiff's motion for a preliminary injunction, and in granting it, to inform the attorneys for the parties that the court would consider its decision tentative, subject to modification or recall should the incoming testimony to the moment of actual signature of the order granting such preliminary injunction justify such action.

III

On the basis of the evidence adduced up to the close of the trial on November 29, 1971, the following appears:

11. The Diapulse Corp. did not bring the seized Diapulse device into compliance with the requirements of the Food and Drug Administration pursuant to the order in the Connecticut suit, made April 25, 1967, amending the judgment entered March 31, 1967, and is, accordingly subject, among other provisions, to subparagraph 4 of the third ordering paragraph of said order reading as follows:

"4. The Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of said article until a duly authorized representative of the Department of Health, Education and Welfare shall have had free access thereto in order to take any sample or make any tests or examinations that are deemed necessary, and shall in writing have released such article for shipment, sale, or other disposition."

12. The Diapulse devices held, manufactured and disposed of by the Diapulse Corp. for a number of years prior to and on and after March 31, 1967, and to the date hereof, were and are substantially similar to the device declared forfeited for misbranding and misrepresentation in the Connecticut action, the differences between the models thereof being in details not pertinent to the issues in the Connecticut or this suit.

13. Notwithstanding the entry of the judgment in the Connecticut action on March 31, 1967, defendant Diapulse Corp. continued to dispose of said Diapulse devices in interstate commerce by sale, lease, gift, grant or other form of disposition through May 1968, misbranded and misrepresented as theretofore.

14. Defendant since said date in May 1968, prior thereto as aforesaid, and subsequently to the date hereof, has been and is now engaged in the business of promoting, selling and introducing and delivering for introduction in

BLEED THROUGH

interstate commerce a device designated as Diapulse, as hereinbefore described, within the meaning of 21 U.S.C. § 321(h) intended for use in the cure, mitigation, treatment and prevention of disease in man and to affect the structure and function of the body of man, and to achieve the therapeutic results without the generation of significant heat.

15. The Diapulse device is claimed to be a pulsed electromagnetic generator which resembles a conventional medical diathermy unit but lacks the energy output of conventional medical diathermy units. It emits its energy in bursts exceeding at such points of emission the output of such conventional unit, and maintains periods of reduced emission or complete lack of emission during intervals between the bursts. The further claim by defendant is that during the period of reduced output the heat generated by the bursts is dissipated, that therapeutic effect is achieved by the penetration of the electromagnetic field of the device into the human body, and that the non-production of heat in consequence of the operation and application of the device to the human body eliminates the possibility of injury to the body from excess heat generated.

The device has, however, been classified as a diathermy unit by the Food and Drug Administration, permitted to operate, and in fact operating on a wave length authorized for comparable diathermy devices, namely, 27.12 megacycles, and

BLEED THROUGH

POOR COPY

deriving its therapeutic value, if any, from the introduction of penetrating heat into the human body.

The determination of the Connecticut suit adjudicated the issue respecting the functioning of the Diapulse device in favor of the Food and Drug Administration, and the additional testimony adduced before this court served merely to show that there were some dissenting views of witnesses based on inconclusive results grounded on inadequate data and conjectures drawn therefrom, with a strong suggestion, at least, that some of the witnesses were pseudoexperts who had been financially corrupted by defendant by cash payments or stock interests in defendant or had had their conclusions colored by a heavy investment in the device which proved economically profitable in the practice of the medical or dental professions.

16. In the interstate sale and distribution of the device defendant has utilized a great many items of written, printed and graphic matter which comprise the labeling of the Diapulse device, including leaflets containing directions for use, instructions, warranty and advertising brochures and advertising layouts, reprints of speeches, and reprints or excerpts of reports and published articles concerning the Diapulse device or implying, by association of the name Diapulse with other matter in said documentation, or ambiguously, that there was a relationship between the functioning and value of

BLEED THROUGH

the device and therapeutic claims asserted in the article or report.

17. In the promotion of the interstate sale and distribution of said Diapulse device, the defendant has organized symposia, sponsored meetings and has had exhibits and sales representatives at meetings of physicians, dentists, and other practitioners or alleged practitioners of the healing arts to whom representations were made by or in behalf of the defendant orally and by labeling as to the mode and mechanism of action of the said Diapulse device and its effectiveness in the treatment of disease and in affecting the functions and structure of the human body.

18. The jury, in the Connecticut forfeiture case against the device, reported in addition to its general verdict of misbranding that the Diapulse device there in controversy was misbranded and misrepresented with respect to its therapeutic value in the treatment of 49 diseases, disorders, and conditions and that false or misleading claims had been made in that regard. Pursuant to the charge of the court that it should select only some of the more significant claims as to which interrogatories were propounded by the court and report on them alone as to their falsity and misleading nature, the jury had left 68 interrogatories unanswered.

The 49 affirmative findings became in consequence res adjudicata and are binding upon this court. Upon close examination, however, of the list of 49 interrogatories thus answered, it is apparent that their scope is so broad that they should be construed as including in their sweep practically all disorders and conditions which afflict the human body or to which it is subject. This conclusion is understandable, for the list is not a scientific one which the Government with the assistance of qualified medical experts prepared, and hence which one/ should be free of overlapping or undue vagueness in its glossary.

It is rather an aggregation of terms which the defendant had in various contexts included in its sales literature with the obvious intent of pushing its product as a panacea for human ailments. It is for that reason that we find included in the enumeration such all-embracing "puffs" as "safe treatment of the entire patient," "stimulating tissue responses and the natural defense mechanism of the body," "restoring good health," "'working up' sick, rundown cells of the body with new life and vigor," "reenergizing the human mechanism,"* and "for giving results where all else has failed." As for huge areas of the body which might be helped, we have "infections," "low back pain," or broader yet, "low back syndrome," "systemic disease," "pelvic inflammatory disease,"

---

* This includes, no doubt, the pitchman's standbys, constipation and impotence.

BLEED THROUGH

"abdominal and pelvic pain and tenderness," "ulceration," "ear conditions," "severe itching," "peripheral vascular insufficiency," and "adrenal malfunction."

Defendant, however, did nothing of consequence to minimize the effect of its advertising activities for some thirteen months after the entry of the Connecticut judgment on March 31, 1967. It continued its distribution of considerable numbers of its machine misbranded as theretofore. On May 6, 1968, several days after the commencement of this action defendant circulated among its distributors a letter in which, with the use of copious full capitals for emphasis, it dealt with the Connecticut judgment as though defendant's disastrous defeat were no more than a standoff with each side gaining a partial victory and implying that what had not been found to have been misrepresented was an affirmative finding that the device had therapeutic value and that defendant's claims of the manner in which the machine functioned applied with respect to the "unadjudicated" diseases or conditions.

At this trial defendant gave evidence, which the court does not credit, that following May, 1968, it modified its literature by excerpting its "permitted" or "approved" claims from brochures, articles, pamphlets, etc. in which, as originally circulated, it had included these claims with others found by the jury to have been misrepresented. Re-

BLEED THROUGH

fendant's witnesses further testified that it had circulated these bowdlerized versions of its literature among its distributors, and that it had made an attempt, which the court finds was either half-hearted or wholly sham, to gather in from its distributors offending literature as yet uncirculated by the distributors among its medical and dental practitioners. No diligent or rigorous effort appears to have been made by Diapulse to reach the practitioners with the modified literature directly, or to advise them at the very minimum that there was a substantial body of scientific opinion which disagreed with the Diapulse corporation's claims. Worse yet, the present owners of the machine and prospective purchasers were not even informed by the Diapulse company that there had been a suit in Connecticut in which the company had been defeated, and some learned this for the first time only on the day they testified in this trial.

The patients, who were being subjected to treatment by the device and were paying for the service at so much per treatment, were left by defendant completely in the dark as to the strong possibility that they were paying for something that the device was incapable of providing.

panoptic view of the proof before this court persuades it (1) that defendant in the sale or other disposition of the device continues to make claims respecting its thera-

BLEED THROUGH

POOR COPY

peutic value which were adjudicated false in the Connecticut suit; (2) that defendant has failed and continues to fail to disclose in its literature that there is at least a very substantial body of medical and scientific opinion which is in complete disagreement with the claims made by defendant concerning the therapeutic efficacy of the Diapulse device; (3) that it has not discontinued its substantial sales, leasing, and other disposition of the device in interstate commerce; (4) that no proof on defendant's part is in prospect which may reasonably, when and if introduced, be expected to alter the court's findings as herein set forth; (5) that this court is not a pharmaceutical house with expertise to delineate the outer limits of claims of therapeutic value of the device and the scientific basis for such claims with the exactitude required in a complex judgment unless it is aided by the processing of the device by the Food and Drug Administration; (6) nor is it, until these claims have been thus delineated and evaluated by said body, in a position to give directions for publicity by the defendant which will not only inform the public as to what, if anything, the machine is capable of, but will have the effect of enlightening the public as to the generally held views of science to the contrary of the company's claims and of cancelling out the influence, based on misbranding and misrepresentation, of literature heretofore circulated by defendant.

BLEED THROUGH

POOR COPY

IV

Order

Inasmuch as the Diapulse device, the propriety of the seizure of which by the Government was adjudicated in the Connecticut action, is substantially identical with the devices and components thereof manufactured by defendant or procured from other manufacturers or contractors by defendant, and disposed of by it to distributors and others in interstate commerce, and said device is presently in the custody of the plaintiff or the Secretary of Health, ducation and Welfare, or its division, the Food and Drug Administration,

It is ORDERED that until the entry of a final judgment in this action or until a further order is entered by this court modifying or revoking the preliminary injunction, whichever is earlier, or until the prior release by a duly authorized representative of the Department of Health, Education and Welfare in writing of the Diapulse device seized in the Connecticut action, which release among other matters releases the device for shipment, sale or other disposition, the defendant, Diapulse Corporation of America, and each and all of its officers, agents, servants, employees and representatives, and all and any persons in active concert or participation with it be and they hereby are restrained and enjoined from causing to be shipped, sold, introduced or delivered for

BLEED THROUGH

POOR COPY

introduction into interstate commerce, or otherwise disposed of, any of said Diapulse devices, assembled or unassembled; and it is further

ORDERED that said release in writing shall be issued by the Secretary only upon compliance on the part of defendant with the provisions of the order amending the Connecticut judgment, which judgment was filed on March 31, 1967, and which amendatory order, made April 25, 1967, was filed April 26, 1967, with leave to the plaintiff and defendant to move this court at the foot of this order for a modification of the dates for the taking of any of the steps provided in said order of amendment in consequence of the lapse of time since the making of said order, or for any other modification or for the revocation of this order.

Further ORDERED that this preliminary injunction is effective in its restraints immediately except as to the ordinary and usual operations of the company and the disposition of the Diapulse devices in the ordinary course of its business, but is to be fully effective in its restraints on and after December 15, 1971, as to the shipment, sale, offer to sell, or other disposition of said Diapulse devices, assembled or unassembled, in interstate commerce.

GEORGE ROSLINS

U. S. D. J.

BLEED THROUGH

POOR COPY

457 F2d 25

UNITED STATES of America,
Plaintiff-Appellee,

v.

DIAPULSE CORPORATION OF AMERICA, also known as the Diapulse Manufacturing Corporation of America, a corporation, Defendant-Appellant.

No. 507, Docket 71-2136.

United States Court of Appeals,
Second Circuit.

Argued Jan. 21, 1972.

Decided March 20, 1972.

Government made motion for preliminary injunction against shipment of subject device in commerce pending relabeling sufficient under Federal Food, Drug, and Cosmetic Act. The United States District Court for the Eastern District of New York, George Rosling, J., granted preliminary injunction, and defendant appealed. The Court of Appeals, J. Joseph Smith, Circuit Judge, held that where the device had been found to be generally misbranded in violation of Federal Food, Drug, and Cosmetic Act and jury of laymen had found 49 specific claims to be false or misleading yet defendant continued its advertising scheme and it did not prove machine's effectiveness or relabel it to the Food and Drug Administration's satisfaction, injunction against defendant from shipping the device in interstate commerce until labeling met standards of the Act to the satisfaction of Food and Drug Administration was not an abuse of discretion.

Judgment affirmed.

1. Drugs and Narcotics ⇨2

The Federal Food, Drug, and Cosmetic Act has as its purpose protection of public from products not proven to be safe and effective for their alleged uses and safeguarding of public health by enforcement of certain standards of purity and effectiveness, and reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction. Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 304, 21 U.S.C.A. §§ 301 et seq., 334.

2. Drugs and Narcotics ⇨2

Passage of Federal Food, Drug, and Cosmetic Act is, in a sense, an implied finding that violations will harm the public and ought, if necessary, to be restrained. Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 304, 21 U.S.C.A. §§ 301 et seq., 334.

3. Drugs and Narcotics ⇨23

District courts are given jurisdiction to restrain violations of Federal Food, Drug, and Cosmetic Act and legislative goals are the framework within which the court operates in deciding whether to grant relief. Federal Food, Drug, and Cosmetic Act, § 302(a), 21 U.S.C.A. § 332(a).

4. Drugs and Narcotics ⇨23

No specific or immediate showing of precise way in which violation of law would result in public harm is required to support court's granting injunctive relief under Federal Food, Drug, and Cosmetic Act. Federal Food, Drug, and Cosmetic Act, § 302(a), 21 U.S.C.A. § 332(a).

5. Drugs and Narcotics ⇨23

Injunction under Federal Food, Drug, and Cosmetic Act may sweep broadly in its prohibition if that is nec-

BLEED THROUGH

POOR COPY

cessary to enjoin future violations which appear likely to occur. Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 302(a), 21 U.S.C.A. §§ 301 et seq., 332(a).

6. Drugs and Narcotics ⇨23

Defendant could not complain that injunction granted against it under Federal Food, Drug, and Cosmetic Act was impermissible because it would put him out of business. Federal Food, Drug, and Cosmetic Act, § 302(a), 21 U.S.C.A. § 332(a).

7. Drugs and Narcotics ⇨23

Where the device had been found to be generally misbranded in violation of Federal Food, Drug, and Cosmetic Act and jury of laymen had found 49 specific claims to be false or misleading yet defendant continued its advertising scheme and it did not prove machine's effectiveness or relabel it to the Food and Drug Administration's satisfaction, injunction against defendant from shipping the device in interstate commerce until labeling met standards of the Act to the satisfaction of Food and Drug Administration was not an abuse of discretion. Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 302(a), 304, 21 U.S.C.A. §§ 301 et seq., 332(a), 334.

8. Drugs and Narcotics ⇨23

Where machine differing only in detail from present models had been condemned because labeling was false and misleading and corrective measures were required before machine could be shipped in commerce, court's order listing as condition for lifting of injunction the approval by Food and Drug Administration of labeling for machine seized in prior in rem action was not improper. Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 302(a), 304, 21 U.S.C.A. §§ 301 et seq., 332(a), 334.

9. Courts ⇨406.3(6)

It is duty of trial judge sitting without jury to appraise testimony and demeanor of witnesses. Fed.Rules Civ. Proc. rule 52(a), 28 U.S.C.A.

10. Judges ⇨51(1)

Where defendant did not allege or show any extrajudicial source of bias, trial court did not deny defendant fair hearing or act on basis of bias or improper motives.

Milton A. Bass, Bass & Ullman, New York City, for appellant.

Cyril Hyman, Asst. U. S. Atty. (Robert A. Morse, U. S. Atty., E. D. N. Y., Alvin L. Gottlieb, Deputy Asst. Gen. Counsel, Food, Drugs and Environmental Health Div., Joanne S. Sisk and Forrest T. Patterson, Attys., Dept. of Health, Education and Welfare, Rockville, Md., of counsel), for appellee.

Before SMITH, FEINBERG and MULLIGAN, Circuit Judges.

J. JOSEPH SMITH, Circuit Judge:

The Diapulse Corporation of America has been prohibited from shipping in interstate commerce the "Diapulse," a pulsed high frequency generator similar to a conventional diathermy unit but with a lower output, intended to create a unique athermal effect, until the labeling meets the standards of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. to the satisfaction of the Food and Drug Administration (FDA). Judge George Rosling of the United States District Court for the Eastern District of New York granted the government's motion for preliminary injunction against shipment of the device on the basis of testimony received in this proceeding and findings in earlier litigation condemning the machine as misbranded. Diapulse appeals. We affirm the judgment of the district court.

Related litigation arising from the marketing of this machine began six years ago. A condemnation action against a Diapulse machine was tried before a jury in Connecticut under 21 U.S.C. § 334. The issue was whether the labeling trumpeting the machine's effectiveness in the cure of 121 "specific" human ailments was false or mis-

BLEED THROUGH

POOR COPY

Opinion Affirming Preliminary Injunction

leading, making the machine misbranded under 21 U.S.C. §§ 352(a), 331(a). The jury returned a general verdict of mislabeling and in addition marked 49 of the claims as specifically misleading. The court instructed the jury that they were not required to pass on all claims; lack of a mark was not an indication that they considered any given claim true.[1]

The Diapulse was condemned as misbranded. Defendant did not take advantage of the opportunity granted to redeem the device by bringing it into compliance with the Food, Drug, and Cosmetic Act (the Act) with guidance from the FDA.[2] In April 1968, the government began this action for injunctive relief under the Act because of alleged continuing violations of the Connecticut judgment.[3] With Diapulse's consent, a preliminary injunction was entered prohibiting the interstate shipment of the device accompanied by claims on the 49 maladies marked by the Connecticut jury.[4] Active prosecution was suspended to allow the company time to submit evidence of effectiveness to the FDA; such was not forthcoming, and after discovery proceedings and much unexplained delay, the case was heard in the fall of 1971. After hearing the bulk of the evidence, the court granted the government's motion for a preliminary injunction against shipment until the labeling was made acceptable under the statute. The trial judge based his conclusions on the fact that the condemned machine differed in detail only from later machines being marketed; that the device was still misbranded under the Connecticut judgment; and that the company had not corrected its earlier material, revealed that medical opinion differed sharply on the therapeutic value of the machine, or altered its advertising and labeling in more than an insignificant way.

[1] Appellant first argues that the court did not consider the correct factors in making the decision on the preliminary injunction. To support this contention it cites numerous cases between private parties. But the function of a court in deciding whether to issue an injunction authorized by a statute of the United States to enforce and implement Congressional policy is a different one from that of the court when weighing claims of two private litigants. The Food, Drug, and Cosmetic Act has

1. The findings on specific claims were elicited in response to interrogatories to the jury, as permitted by Rule 49(b) of the Federal Rules of Civil Procedure. The court's instruction that the jury did not have to consider all the claims separately was approved by this court on appeal. United States v. Diapulse Manufacturing Corp. of America, 389 F.2d 612 (2d Cir.), cert. denied, An Article of Device . . . Diapulse Mfg. Corp. of America v. United States, 392 U.S. 907, 88 S.Ct. 2060, 20 L.Ed.2d 1365 (1968). For more detail on the factual background, see that opinion, and United States v. Diapulse Manufacturing Corp. of America, 269 F.Supp. 102 (D.Conn.1967).

2. Diapulse claims that the FDA refused to cooperate or consider its impressive evidence; a review of the relevant papers indicates that the FDA would not accept clinical observations as the equivalent of reliable studies of the device's functioning and effectiveness, and that it was justified in that conclusion.

3. Seizure actions are *res judicata* and affect the article wherever it is introduced into interstate commerce in violation of the statute. United States v. 216 Bottles, More or Less, Sudden Change, 36 F.R.D. 695 (E.D.N.Y.1965). And the adjudication in an *in rem* action is *res judicata* in an injunction suit. United States v. Nysco Laboratories, 318 F.2d 817 (2d Cir. 1963).

4. As the court below noted, barred as the company was from claiming that the device worked by "stimulating tissue responses and the natural defense mechanisms of the body," "perking up sick and run-down cells of the body with new life and fresh vigor," or that it cured, among other ills, "systemic infections," "abdominal pain and tenderness," "hypertension," and "adrenal malfunctions," it must have known it was violating the Connecticut decision with its continued use of labeling which promised aid in the cure of any human disease, much less the 72 ailments it specifically mentioned.

BLEED THROUGH

POOR COPY

as its purpose the protection of the public from products not proven to be safe and effective for their alleged uses and the safeguarding of the public health by enforcement of certain standards of purity and effectiveness. The reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction. United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969); United States v. Sullivan, 332 U.S. 689, 68 S.Ct. 331, 92 L.Ed. 297 (1948); Pasadena Research Laboratories v. United States, 169 F.2d 375 (9th Cir.), cert. denied, 335 U.S. 853, 69 S. Ct. 83, 93 L.Ed. 401 (1948); United States v. 250 Jars, etc. of United States Fancy Pure Honey, 218 F.Supp. 208 (E. D.Mich. 1963). As the Supreme Court said in United States v. Dotterweich, 320 U.S. 277, 64 S.Ct. 134, 88 L.Ed. 48 (1943):

> The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [320 U.S. at 280, 64 S.Ct. at 136]

[2-4] The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, be restrained. *See* United States v. City and County of San Francisco, 310 U.S. 16, 60 S.Ct. 749, 84 L.Ed. 1050 (1940). The district courts are given jurisdiction to restrain violations of the statute (21 U.S.C. § 332(a)); the legislative goals are the framework within which the court operates in deciding whether to grant injunctive relief. Hecht Co. v. Bowles, 321 U.S. 321, 64 S.Ct. 587, 88 L.Ed. 754 (1944). No specific or immediate showing of the precise way in which violation of the law will result in public harm is required. Shafer v. United States, 229 F.2d 124 (4th Cir.), cert. denied, 351 U.S. 931, 76 S.Ct. 788, 100 L.Ed. 1460 (1956); Walling v. Brooklyn Braid Co., 152 F.2d 938 (2d Cir. 1945); United States v. Ingersoll-Rand Co., 218 F. Supp. 530 (W.D.Pa.), aff'd 320 F.2d 509 (3d Cir. 1963). Thus, Diapulse's claim that a removal from commerce is not justified because there was no showing of irreparable injury or proof that the machine was unsafe is beside the point.[5] In any case, the company's perspective in defining "unsafe" or "injury" is too narrow. As the court said in reviewing the labeling of a product called Mucorhicin in United States v. Nutrition Service, Inc., 227 F.Supp. 375 (W.D.Pa. 1964), aff'd 347 F.2d 233 (3d Cir. 1965):

> [T]hat does not mean that because such evidence [of unsafeness] has not been introduced, that the hope held out by the producers of Mucorhicin to the medically aidable patients may not induce them to delay medical treatment by competent doctors to the extent that they become less capable or incapable of being aided, and so cause irreparable public injury. . . . Congress intended that all persons in the national domain be protected against any such injury. . . . [227 F.Supp. at 388]

[5, 6] The other major consideration in the trial court's exercise of discretion is the likelihood of continuing vio-

[5] Nor is there any validity to the company's claim that the injunction provision is meant to be used only in emergencies. On the contrary, the legislative history indicates that the seizure provisions were intended for use in such situations, and the injunction section was to be utilized "in border-line cases that cannot be settled without litigation." H.R.Rep.No.2139, 75th Cong., 2d Sess. 3 (1938). It was intended for cases such as the present one, in which the manufacturer refused to remove from circulation labeling found to be false and misleading.

Opinion Affirming Preliminary Injunction

lation or recommencement of the offensive behavior, if it has ceased during the pendency of the litigation. "The matter is in the broadest sense for the discretion of the trial court which is best qualified to form a judgment as to the likelihood of a repetition of the offense . . . '[H]is discretion is necessarily broad and a strong showing of abuse must be made to reverse it.' United States v. W. T. Grant Co., 345 U.S. 629, 633, 73 S.Ct. 894, 898, 97 L.Ed. 1303." United States v. Article of Drug . . . Designated . . . Complex Cholinos Capsules, 362 F.2d 923, 928 (3d Cir. 1966); *see* United States v. Nysco Laboratories, Inc., 215 F.Supp. 87 (E.D.N.Y.), aff'd 318 F.2d 417 (2d Cir. 1963). The injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur. May Dept. Stores Co. v. NLRB, 326 U.S. 376, 66 S.Ct. 203, 90 L.Ed. 145 (1945); United States v. Nysco Laboratories, Inc., *supra*. Nor can appellant complain that the injunction is impermissible because it will put him out of business. He "can have no vested interest in a business activity found to be illegal. It has long been settled that the [Food and Drug] Act itself is a constitutional exercise of the commerce power. United States v. Walsh, 331 U.S. 432, 67 S.Ct. 1283, 91 L.Ed. 1585 (1947)." United States v. Ellis Research Laboratories, Inc., 300 F.2d 550, 554 (7th Cir. 1962).

[7] A consideration of the facts in this case in light of the above leads to the inescapable conclusion that the issuance of the injunction was warranted. The device had been found to be generally misbranded, in violation of the statute, and in addition, a jury of laymen had found 49 specific claims to be false or misleading. Yet the company continued its brazen advertising scheme, failing to inform its buyers and lessors of the litigation or of the dispute in medical circles about the machine's efficacy. It did not prove the machine's effectiveness or relabel it to the FDA's satisfaction. The company's persistence in marketing the device makes it highly likely that the prohibited activity will cease only on the issuance of a blanket prohibition on shipment.

Taking into account the fact that a final decision on the merits after a full trial would have to await transcripts and would therefore not be forthcoming in the near future, the district court concluded that it was necessary to take appellant's "welter of intermingled true, half-true, and false promotional material out of the mainstream of medicine." We agree that the action was justifiable and was not an abuse of discretion.

[8] The court's order listed as a condition for the lifting of the injunction approval by the FDA of labeling for the machine seized in the *in rem* action. Diapulse claims that this imposes a requirement of "pre-clearance" of the device with the FDA and that such pre-clearance is not required under the law before a device can be manufactured and shipped. The circumstances of this litigation make analogy to pre-clearance less than persuasive. Diapulse is not attempting to market the machine for the first time; on the contrary, a machine differing only in detail from present models has been condemned because the labeling was false and misleading. Corrective measures are required before the machine can be shipped in commerce. The court below found, following the order in the Connecticut action, that the FDA, the administrative agency charged with implementation of the statute which the company was found to be violating, was the best qualified to assess and formulate, with the company, labeling that is not false or misleading. The court itself is not expert on the medical and scientific issues which must be explored in order to produce accurate labeling; the assignment of that function to the FDA is sensible and proper. Cf. United States v. Allan Drug Co., 357 F.2d 713 (10th

BLEED THROUGH

POOR COPY

...ir 1966).[8] The order does not leave the company in doubt about what acts are prohibited or the methods by which it can proceed to correct its violations.

Appellant's last claim is that the district court was biased and improperly assessed the credibility of its witnesses and the value of its device. The court was certainly harsh in his assessment of the appellant's witnesses. He informed counsel that he did not give much credence to testimony based solely on clinical experience with a device that was a substantial investment for a practitioner; he felt that there was a human tendency to persuade oneself in such a situation that the investment was worthwhile. He stated in no uncertain terms that he did not credit highly the testimony by doctors or researchers who had been paid, or whose affiliated colleges had been paid, with Diapulse stock. The court suggested that the witnesses were only repeating the testimony they had given in Connecticut years before and he questioned the application of the term "expert" to them.

[9] None of these conclusions, in itself, goes beyond what is proper for a trial judge when he is sitting without a ... must give "due regard to the opportunity of the ...court to judge of the credibility ...the witnesses." Rule 52(a), Fed.R. ... It is his duty to appraise the ...mony and demeanor of the witness... United States v. Oregon State Med... ..., 343 U.S. 326, 72 S.Ct. 690, ... Ed. 978 (1952); Omega Importing ... Petri-Kine Camera Company, ... F.2d 1190, 1197 (2d Cir. 1971); ... Federal Cartridge Corp., ... 81 (8th Cir. 1946). The man... which the court presented his ob... however, was quite abrasive. ...ing comments were often ...e directly to the witnesses, and lacked the restraint a trial judge ought ideally to show, no matter what he thinks of the value of the testimony.

The court was not unprovoked, however. Diapulse was presenting highly repetitious testimony; no significant evidence had been developed since the Connecticut trial, and the company apparently refused to believe that the latter had *res judicata* effect. And the "studies" Diapulse relied on were merely clinical observations, not double blind tests done under controlled conditions with accurate record keeping. The court, however, might well have held these opinions and expedited the presentation of testimony without being so caustic to the parties appearing before him.

[10] Despite the comments of the court, we do not find bias or denial of a fair hearing. Appellant does not allege or show any extra-judicial source of bias, and that is essential to sustain a charge of bias in this circuit. Wolfson v. Palmieri, 396 F.2d 121, 124 (2d Cir. 1968). And the alleged "prejudgment" of the case was no more than the court's statements, at the time of decision on the preliminary injunction, about his conclusions based on the evidence he had received at that time, and essential to his decision on preliminary relief. The court did make one remark apparently inconsistent with his declarations of openmindedness on the ultimate issues in the case. In his opinion he described the Diapulse machine once as "nontherapeutic;" appellant claims that he had decided that Diapulse could never be relabeled as it was not therapeutic at all. The remark in the opinion is ambiguous; it may have referred only to its efficacy in light of the claims then being made for it, for other parts of the opinion and his comments during the trial clearly indicate that he had not prejudged this or the other issues remaining in the litigation.

... United States v. Sars of Louisiana, ... F.Supp. 307 (E.D.La.1971), in ... the court found that compliance ... recommendations made by FDA inspectors to the defendant removed the necessity for issuance of an injunction against shipment of products produced at his plant.

Opinion Affirming Preliminary Injunction

We conclude that the court applied the proper standard for issuance of a preliminary injunction authorized by this statute, that the facts amply warranted the order of cessation of appellant's illegal practices until the labeling was corrected, and that the court, although perhaps overly abrasive, did not deny appellant a fair hearing or act on the basis of bias or improper motives.

We have considered appellant's other contentions and find no merit therein.

Judgment affirmed.